FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

1001–1050

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

WATSON B. MILLER, *Acting Administrator, Federal Security Agency.*

WASHINGTON, D. C., *December 12, 1944.*

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DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

1001. Action to enjoin and restrain distribution of Sekov products. U. S. v. Sekov Corporation and Hazel Ruth Vokes (Sekov Studios). Permanent injunction granted. (Inj. No. 53.)

On April 17, 1943, the United States attorney for the Southern District of California filed a complaint for injunction against the Sekov Corporation and Hazel Ruth Vokes, trading under the name of the Sekov Studios, Hollywood, Calif. (The complaint also joined as party defendant Edwin Hoskin Vokes, but after hearing, the court ruled that it did not have jurisdiction over that person.)

The complaint alleged: (1) That the defendants were engaged in the manufacture of various capsules which contained desiccated thyroid, which were designated by the names "Sekov," "Sekov Reducer," "Sekov Reducer for Men," "Sekov Formula P," "Sekov Formula R," and "Sekov Formula T," and which were being introduced and delivered for introduction into interstate commerce in capsule form, for sale to the general public for self-medication in the treatment of obesity.

(2) That "Sekov" and "Sekov Reducer" each consisted of two types of capsules, designated as Capsule No. 1 and Capsule No. 2; that the No. 1 capsules contained glandular material including thyroid, the thyroid content varying from 1.87 grains to 2 grains per capsule, the recommended dosage suggested being 1 capsule before the noon meal; that the No. 2 capsules contained rhubarb, cascara sagrada, asafetida, and other ingredients, the recommended dosage being 1 capsule every other night (just before retiring); that the "Sekov Reducer for Men" consisted of 2 types of capsules, the No. 1 containing, in addition to other ingredients, thyroid and aloin, the thyroid content varying from 1.84 grains to 1.95 grains per capsule, the dosage recommended being "One capsule morning and one capsule evening (preferably half to one hour before meals)"; that the No. 2 capsule was identical with the "Sekov Reducer" No. 2 capsule, and the dosage recommended was "One capsule every night (just before retiring)"; that the "Sekov Formula P" contained, in addition to other ingredients, thyroid in an amount of approximately 1.73 grains per capsule; that the "Sekov Formula R" contained ingredients similar to the "Sekov Formula P," with a thyroid content of approximately 1 grain per capsule; that the "Sekov Formula T" contained ingredients similar to the "Sekov Formula P," with a thyroid content of 1.87 grains per capsule; and that the dosages recommended in the labeling of formulas "P," "R," and "T," were identical, "One capsule per day—taken ½ to 1 hour before morning meal."

*For omission of, or unsatisfactory, ingredients statements, see Nos. 1003, 1005, 1009, 1010, 1011, 1022, 1043, 1044; deceptive packaging, Nos. 1003, 1011; failure to bear accurate statement of quantity of contents, Nos. 1003, 1009, 1010, 1033, 1034, 1040, 1043, 1047, 1049; contamination with filth, No. 1011; cosmetics, subject to the drug provisions of the Act, Nos. 1021, 1040, 1043, 1047.

(3) That on February 17, 1940, on complaint of the Federal Trade Commission a preliminary injunction was issued by the United States District Court for the Southern District of California, enjoining the Sekov Corporation, Edwin Hoskin Vokes, and Hazel Ruth Vokes, as officers of the corporation and as individuals trading as "Sekov Reducing Studios," their agents, etc., from causing to be disseminated any advertisement by any means tending to induce the purchase in interstate commerce of the drug sold under the name of "Sekov Reducer", or "Sekov," or any other name, which advertisement represented directly or indirectly that such preparations were a safe, competent, and scientific treatment for obesity; and that on March 12, 1940, the Federal Trade Commission issued a complaint against the Sekov Corporation, Edwin Hoskin Vokes, and Hazel Ruth Vokes, as officers of the corporation and as individuals trading as "Sekov Reducing Studios," and on September 8, 1940, pursuant to a stipulation of facts, the Federal Trade Commission issued its order against the defendants to cease and desist from, directly or indirectly, doing, among other things, disseminating or causing to be disseminated any advertisement, (a) by means of the United States mail, or (b) by any means in commerce, as commerce is defined by the Federal Trade Commission Act, which advertisement represented directly or through individuals that said preparation was a safe, competent, and scientific treatment for obesity.

(4) That on July 21, 1941, a libel had been filed in the District Court of the United States for the Southern District at Houston, Texas, against capsules similar to those aforesaid, and on May 28, 1942, final judgment was entered ordering the libeled articles destroyed. On June 5, 1942, a little more than a month after the decision of the Texas court, the defendant shipped to Houston, Texas, a stock of drug products similar to those condemned by the Texas court, and a libel was filed by the United States against this shipment on July 29, 1942, to which an answer was filed by the Sekov Corporation. At the pre-trial hearing on October 24, 1942, counsel for the claimant, the Sekov Corporation, agreed to stipulate that the facts alleged in the libel were true, excepting the question of misbranding. On or about January 8, 1943, the defendants, trading as "Sekov Studios," shipped 6 cartons of Sekov to Reno, Nev., labeled "Manufactured for—Packed by—Sekov Corporation," and a libel was filed against this shipment on March 6, 1943, in the District Court of the United States for the District of Nevada.

(5) That the products were misbranded as follows: (a) that the "Sekov Reducer," "Sekov Formula T," and "Sekov Reducer for Men" were dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, or suggested in the labeling (this allegation was based on the fact that the capsules, when taken according to the directions, would supply a dangerous amount of thyroid); (b) in that the label on the carton of each of the preparations, including the design of a slender female figure, was false and misleading since it created the impression that the articles were safe and appropriate treatments for the reduction of weight, whereas they were not safe and appropriate treatments, but were dangerous drugs and could not be depended upon to reduce weight; and (c) that the "Sekov Formula P" and "Sekov Formula R" were misbranded in that the label on each carton, including the design of a slender female figure, was false and misleading since it created the impression that the articles were dependable and appropriate treatments for the reduction of weight, whereas they were not dependable and appropriate treatments, and could not be depended upon to reduce weight.

(6) That the defendants had attempted and were still attempting to circumvent the protection intended to be given for the health and welfare of the public, and that the Government had endeavored to have the defendants refrain from shipping the aforesaid products in interstate commerce, without success, over a period of years, and, by reason of the failure of the defendants to refrain from shipping the products, it became necessary for adequate protection to the general public that the defendants be forever enjoined from shipping such misbranded products in, or introducing or delivering them for introduction into, interstate commerce to be used as food or drugs.

On April 19, 1943, the court issued a temporary restraining order and an order to show cause why, pending final determination, a preliminary injunction should not be entered. On May 3, 1943, the court denied the motion for a preliminary injunction and the case was set for trial. On June 12, 1943, after hearing the testimony, the court gave its opinion in the following minute order:

LEON R. YANKWICH, *District Judge*:

"The above-entitled cause heretofore tried and submitted, is hereby decided as follows:

"Judgment is ordered entered for the plaintiff as prayed for in its complaint, restraining and enjoining the defendants, their servants, agents, officers, employees, attorneys and assigns, and each of them, from the introduction or delivery for introduction into interstate commerce of any of their said products herein before designated and described as 'Sekov', 'Sekov Reducer', 'Sekov Reducer for Men', 'Sekov Formula P', 'Sekov Formula R', and 'Sekov Formula T,' in violation of or contrary to Title 21, U. S. C. A., Sections 301 to 392.

"I am of the view that the evidence shows clearly that the preparation is misbranded because 'it is dangerous to health when used in the dosage or with the frequency or duration prescribed and recommended or suggested in the label thereof.' (21 U. S. C. A. Sec. 352 (j).) Even the physicians who testified for the defendants admitted that the use of thyroid extracts in the quantity prescribed by obese persons, whose obesity *was not due* to hypothyroidism, might prove injurious to health. The physicians who testified for the Government, each of whom is an expert in his field, were emphatic in their statement that such use not only might be detrimental, but in all likelihood would be so. If the defendants limited sales to persons who are suffering from obesity due to hypothyroidism,—either by requiring a physician's certificate to that effect, or by conducting an examination of the person before making a sale, it could well be contended that, with such precaution, any detrimental results would be only those incident upon any selfmedication, which the law does not prohibit. As the sale is not made through general outlets, but through agencies conducted by the defendants—studios located in various cities throughout the United States, such safeguards could easily be enforced. As it is, the record shows that any obese person who calls at one of these studios can obtain the product without any inquiry as to whether the conditions for which the product is intended as a remedy, co-existing obesity and hypothyroidism,—are present. In view of this, the statement on the carton that the preparation is 'a reducer for overweight due to a thyroid deficiency' and similar statements in the pamphlet are inadequate to forestall the evil inherent in the use of this preparation by persons whose hypothyroidism has not been established by a competent physician. It is to be noted, as stated by me during the argument, that nowhere is there a warning couched in imperative negatives such as are found in products which may have a deleterious effect. Nowhere is there a statement '*Do not use this* unless a physician has told you that your obesity is due to hypothyroidism'. The reference to the consultation of a physician is ineffective. It reads: 'We recommend that you consult physician to determine the cause of your overweight as the use of THYROID by a person not deficient in THYROID may result in serious or irreparable injury to the health of the user'.

"I am also satisfied that the contra-indications are inadequate. In the light of the expert testimony, I do not think that the average person seeking to reduce would be competent to detect the evils resulting from its use. Bearing in mind that the defendants in their advertising and literature, appeal especially to the vanity of women, I am of the view that the average woman, in her desire to achieve a beauty of form, would be more inclined to consider the manifestations of ill effect as the natural price to pay for the results to be achieved. So that if we consider the warnings in relation to the persons to whom they are addressed, as counsel bids us to, it is quite evident that they are ineffective for the purpose."

On June 25, 1943, the court handed down findings of fact substantially sustaining the allegations in the complaint, and conclusions of law sustaining the prayer of the complaint. On the same day a decree for permanent injunction was filed, ordering the defendants forever restrained and enjoined from introducing or delivering for introduction into interstate commerce any of their products designated and described as "Sekov," "Sekov Reducer," "Sekov Reducer for Men," "Sekov Formula P," "Sekov Formula R," and "Sekov Formula T."

1002. Misbranding of Sekov Reducer. U. S. v. 15 Cartons of Sekov Reducer. Tried to the court without a jury. Judgment for the Government. Decree of condemnation and destruction. (F. D. C. No. 5167. Sample No. 11274–E.)

Misbranding of Sekov and adulteration and misbranding of Sekov Formula "P." U. S. v. 47 Cartons and 6 Cartons of Sekov and 7 Cartons of Sekov Formula "P." Default decrees of condemnation and destruction. (F. D. C. Nos. 7992, 7993, 9500. Sample Nos. 11077–E, 11078–E, 11056–F.)

On July 21, 1941, July 29, 1942, and March 6, 1943, the United States attorneys for the Southern District of Texas and the District of Nevada filed libels against 62 cartons of a product labeled "Sekov," or "Sekov Reducer," and 7 cartons of Sekov Formula "P" at Houston, Tex., and 6 cartons of Sekov at Reno, Nev., al-

leging that the articles had been shipped in interstate commerce within the period from on or about May 24, 1941, to January 8, 1943, by the Sekov Corporation or Sekov Studio, from Hollywood, Calif.; and charging that they were misbranded and that the Sekov Formula "P" was also adulterated.

Examination showed that each carton of the Sekov, or Sekov Reducer, contained two types of capsules, "No. 1" and "No. 2," respectively. Analyses of samples showed that the "No. 1" capsules consisted of glandular material including thyroid in amounts ranging from 1.84 grains to 1.95 grains per capsule; that the "No. 2" capsules contained rhubarb root, cascara sagrada bark, aloin, and asafetida; and that the Formula "P" contained approximately 1.73 grains of thyroid per capsule.

The products were alleged to be misbranded (1) in that the labeling was false and misleading; (2) in that the articles were dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling; and (3) (portions) in that their labelings failed to bear adequate directions for use, and such adequate warnings as are necessary in case of thyroid and laxative preparations. (The misbranding charges are more fully set forth in the opinion of the court below.)

The Formula "P" was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess, since it was represented to contain "Active Ingredients Thyroid, U. S. P. 1 Gr.," whereas it contained more than 1 grain of U. S. P. thyroid per tablet.

The Sekov Corporation of Los Angeles, Calif., filed its claim and answer in the Southern District of Texas to the libel involving 15 cases of "Sekov Reducer," and filed a motion for removal of the case to the Southern District of California. On September 18, 1941, the court denied this motion, handing down the following opinion:

KENNERLY, *District Judge*:

"This is a suit by the United States of America to condemn under the Federal Food, Drug and Cosmetic Act of June 25, 1938 (Title 21, Sections 301 to 392, U. S. C. A.), Fifteen Cartons, more or less, of articles called 'Sekov Reducer.' Such articles were at the time of the filing of said suit, and are now, situated in the City of Houston in this Division and District. They have been seized by the Marshal. His Return shows that they were in possession of Sekov Reducing Studio when seized.

"Sekov Corporation, a claimant of such articles (for convenience called Claimant), has filed a Motion to transfer the suit to the District Court of the United States in the District in which Claimant says it has its principal place of business, i. e., Hollywood, in the Southern District of California. This is a hearing on such Motion under Local District Court Rule 25. The matter is to be determined from the pleadings of the parties which for the purpose of this hearing will be regarded as stating the facts.

"1:—The particular provision of such Act upon which Claimant relies to support such Motion is the following portion of Section 334, Title 21, U. S. C. A.:— 'In any case where the number of libel for condemnation proceedings *is limited* as above provided the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial.'

"The Government answers the Motion with the claim that in this case the number of libel for condemnation proceedings *is not limited* under that portion of Section 334 which reads as follows:—

'(a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce, or which may not, under the provisions of section 344 or 355, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found: Provided, however, That no libel for condemnation shall be instituted under this chapter, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this chapter based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such

proceeding is so pending, except that such limitations shall not apply:— * * *
'(2) when the Secretary has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Department that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer.'

"I think the Government is right, and that this is not a case that may be transferred.

"2:—It will be observed also from Section 334 that a claimant such as is the Claimant here is not necessarily entitled to have the case transferred to the District in which it has its place of business, but only a District of 'reasonably proximity' thereto. But that such transfer shall take place unless good cause to the contrary is shown.

"Not only is this a case where proceedings are not limited, but good cause is shown why it should not be transferred. It not only appears that the articles are situated in this District, but were in the hands of a person other than claimant when seized and that many of the witnesses are in this District.

"Claimant's motion will be denied. Let an Order be prepared and presented accordingly."

On April 13, 1942, the case against the 15 cartons at Houston, Tex., came on for trial before the court, and on April 30, 1942, the court found all issues of fact and law for the Government, handing down the following opinion:

KENNERLY, *District Judge*:

"This is a libel by the United States Government under the Federal Food, Drug and Cosmetic act (Sections 301 to 392, Title 21, U.S. C. A.), to condemn Fifteen Cartons, more or less, of Sekov Reducer, a claimed remedy for obesity, found and situated in this District and Division, alleged to be misbranded within the meaning of the Act, and to have been shipped on or about May 24, 1941, in Interstate Commerce by Sekov Corporation, Hollywood, California, to Sekov Reducing Studio, Houston, Texas, for sale by such Studio. The Sekov Corporation (for brevity called Claimant) is here, claiming such articles, denying the allegations of the Government, and contending for immunity here because, as it says, the Federal Trade Commission in a proceeding before it has heretofore assumed jurisdiction of and decided the questions here involved.

"It has been stipulated that the articles sought to be condemned were shipped in Interstate Commerce for sale in this District and Division as alleged, that they have been seized, and the Complaint and Order in the proceedings before the Federal Trade Commission are in evidence. Thus we are brought at once to the questions to be determined.

"1:—The Government complains with respect to such articles as follows:—'Said article is misbranded in violation of the Act of June 25, 1938, known as the Food, Drug and Cosmetic Act, in that the statement on the carton 'Reducer' and the design of a slender female figure are false and misleading, since they imply that the article is a safe and appropriate treatment for the reduction of weight, when in fact the article is not such a safe and appropriate treatment but is a dangerous drug and does not constitute an effective agent in reducing weight.'

"This complaint is bottomed on that part of the Act reading as follows (Section 352 (a), Title 21, U.S. C. A.):—'A drug or device shall be deemed to be misbranded: * * * If its labeling is false or misleading in any particular.'

"On the outside of the container or package of 'SEKOV' are these words:—'SEKOV Trade Mark Reg. U. S. Pat. Off. REDUCER (Then follows a picture of a woman with a slender figure) Manufactured for—Packed by 6404 Hollywood Blvd—Sekov Corporation—Hollywood, California.'

"'Sekov' comes in and is to be taken in two capsules, stated on the label to contain and which the evidence shows do contain ingredients as follows:—'No. 1 Capsule Active Ingredients Thyroid, U. S. P. 1.87 Gr. Whole Ovarian Whole Pituitary Aloin No. 2 Capsule Active Ingredients Rhubarb Powder Asafetida Cascara Sagrada Oleoresin Ginger Aloin-Bile Salts.'

"I find the labeling false and misleading. The evidence clearly shows that 'Sekov' is not a reducer, i. e., that it is not a remedy for obesity and will not reduce the weight or figure of a heavy or stout woman to the slender proportions shown in the picture on the container.

"It is shown that the Sekov Reducing Studio, Houston, was furnished by Claimant with a supply of printed booklets, the title of which is 'Sekov, A Path to Slenderness'. These booklets were shipped to the studio in Interstate Commerce and kept on hand by the Studio in Houston and sent or delivered to persons making inquiry by mail or in person with respect to 'Sekov'. The evidence is not

convincing that one of these booklets went to every purchaser of 'Sekov.' Citing United States v. Research Laboratories, Inc. (U. S. C. A. Ninth decided February 24, 1942, — Fed. (2d) —), Claimant says that such booklets under Section 201 (m) of the Act (Section 321 (m), Title 21, U. S. C. A.) must be considered as part of the label. Citing United States v. 59 Tubes, 32 Fed Supp. 960, the Government combats this view. Which is right, I do not find it necessary to decide, because the booklets, if construed as part of the label, do not help Claimant, but support the Government's contention. The front outside cover of the booklets introduces 'Sekov' as 'A path to SLENDERNESS' and shows the same picture of a slender woman shown on the container. It is then said, 'A Reducing Formula,' 'No Rigid Diet,' 'No Strenuous Exercises.' The back outside cover and the inside of the booklets contain similar statements, also two pictures of a very stout woman and a very slender woman, purporting to show 'before' and 'after' use of 'Sekov.' They also contain four strong testimonials from women, praising 'Sekov' as a flesh reducer, one claims the writer was reduced from 212 to 128 pounds, another from 149 to 130 pounds, another from 164½ to 135 pounds, and still another from 145 to 123 pounds. There are some rather obscure statements in the booklets that 'Sekov' contains thyroid and is a treatment for obesity only when used by persons suffering from hypothyroidism (lack of thyroid), but the booklets, considered as a whole, strongly affirm 'Sekov' is a reducer and a cure for obesity generally.

"Whether the label on the container is considered alone or in connection with the booklets, it is false and misleading within the meaning of the Act.

"Standing on George H. Lee & Co., v. Federal Trade Commission, 113 Fed. (2d) 583, Claimant says the order of the Federal Trade Commission renders it immune here. The Government combats this view. I find it unnecessary to decide the question thus raised, because a fair construction of the Order of the Commission [1] and the Findings of Fact and Conclusions of Law therein supports the contention of the Government, and the finding here that the labeling is false and misleading.

"2:—The Government, in its Libel, also complains with respect to such articles as follows: 'Said article is further misbranded in that it is dangerous to health when used in the dosage, or with the frequence or duration prescribed, recommended or suggested in the labeling thereof, namely, (on the carton): '30-No. 1 Capsules THIRTY DAYS SUPPLY * * * No. 1 One Capsule before Noon Meal.' This allegation is based on the fact that the capsules when taken in accordance with the suggested directions will supply a dangerous amount of thyroid.'

"This complaint is bottomed on that part of the Act reading as follows (Section 352(j), Title 21, U. S. C. A.):—'A drug or device shall be deemed to be misbranded: * * * (j) If it is dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.'

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[1] A part of the Order of the Commission is as follows: "The aforesaid statements, claims, and representations used and disseminated by the respondents in the manner above described are grossly exaggerated, misleading and untrue. In truth and in fact, said preparation advertised and known as "SEKOV REDUCER" and as "SEKOV" is not a scientific treatment for obesity when administered without a thorough medical examination and without scientific care and observation, and constitutes a treatment for obesity only when used by persons suffering from hypothyroidism. Obesity may be due to several causes, including the dysfunctioning of the pituitary gland and to excess intake of food, in which cases the use of said preparation will be improper and ineffective. Said preparation will not guard the health of the user and does not act on a corrective principle for the reason that the effect of the intake of thyroid accelerates the rate of metabolism whereby the tissues, especially fatty tissues, are burned more rapidly than is normal, and such a process may be dangerous and may be injurious to the health and life of the user unless the extent of such process is carefully coordinated to the exact needs of the person suffering from hypothyroidism. The use of said preparation is a harsh or strenuous method of reducing for the reasons herein set forth. Said preparation does contain cathartics and dangerous drugs in that Capsule No. 1 of said preparation contains rhubarb, cascara sagrada, aloin and bile salts, all of which are cathartics, and all of which tend to dehydrate the body tissues. In addition said preparation contains the dangerous drug, extract of thyroid. Said preparation is not made for reaching the glands or nourishing the glands whose faulty function is the cause of most overweight. The only gland substances in said preparation are whole ovarian substance, whole pituitary substance and thyroid substance, and the effect of thyroid gland substance is to supply thyroxin to the system but not to rejuvenate the thyroid gland. Said preparation does not regulate the action of the glands gently and gradually or at all. The use of said preparation, although it may result in taking off fat by accelerating the rate of metabolism, may seriously weaken the body and the organs of the body, including the heart. Said preparation is not effective in reducing practically all cases of overweight for the reason that the drug extract of thyroid is effective only in treatment of obesity in cases in which the patient is suffering from hypothyroidism. Most overweight is caused by excessive intake of food. Said preparation does not accomplish reduction of weight or fat by normalizing the body."

"The dosage and directions for taking 'Sekov' are found on the container or cover of the package. On the outside of the container, there are these directions:—'(30-No. 1 Capsules) Thirty Days Supply (15 No. 2 Capsules) Price $5.50 Adequate directions for use on inside cover of package.'

"On the inside of the package or container, there are found these directions:—'No. 1 One Capsule before Noon Meal (Preferably half to one hour before) Not to be used by persons suffering from hyperthyroidism. No. 2 One Capsule Every Other Night (Just before retiring) Important not to be used when abdominal pain (stomach ache, cramps, colic), nausea, vomiting (stomach sickness) or other symptoms of appendicitis are present.'

"The evidence supports and compels a finding and I find, that 'Sekov' is dangerous to health when used in the dosage or with the frequency or duration prescribed in the quoted directions on the label, and this is true whether the patient is or is not suffering from hyperthyroidism or from hypothyroidism.

"In the hereinbefore mentioned booklets which Claimant says must be considered as a part of the directions, it is said:—'Sekov contains Thyroid and constitutes a treatment for obesity only when used by persons suffering from hypothyroidism. (Lack of Thyroid) We recommend that you consult physician to determine the cause of your overweight as the use of Thyroid by a person not deficient in Thyroid may result in serious or irreparable injury to the health of the user.'

"If, as Claimant contends, the booklets must be looked to as part of the label, there is no change in the findings. I do not think Claimant's case is helped when the booklets are considered as a whole.

"The question arises again as to the effect here of the Order of the Federal Trade Commission in evidence and upon which Claimant relies upon for immunity. The Order contains findings that 'Sekov' is not a scientific treatment for obesity as claimed, when administered without a thorough medical examination and without scientific care and observation of the patient, and that it constitutes a treatment for obesity at all only when used by persons suffering from hypothyroidism. And that it may be dangerous and may be injurious to the health and life of the patient unless carefully coordinated to the exact needs of the person suffering from hypothyroidism. If, as Claimant insists, this Court is bound by such Findings, Claimant's case is not helped.

"It is not necessary to discuss other questions raised by the pleadings. From what has been said, it follows that the Government is entitled to Judgment, condemning such articles."

On May 28, 1942, judgment of condemnation was entered. The case was appealed to the Circuit Court of Appeals for the Fifth Circuit, and on December 8, 1943, the judgment of the District Court was affirmed, the court handing down the following opinion:

McCord, *Circuit Judge:*

"The appeal is from a judgment condemning fifteen cartons of Sekov Reducer, an alleged remedy for obesity. The trial court found that the product had been falsely labeled and misbranded and shipped in interstate commerce contrary to the provisions of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A. Par. 301 et seq., par. 334, par. 352 (a), (f) and (j). The findings of fact and conclusions of law of the trial court are included in a published opinion, United States v. fifteen Cartons, more or less, of Sekov Reducer, D. C. F. Supp. 52.

"The Sekov Reducer containers bore a picture of a woman with a slender figure. Printed booklets intended for distribution with the product were titled "Sekov, A Path to Slenderness." The labels on the packages, and the booklets which appellant alleges were distributed to purchasers, were false and misleading in that they represented Sekov Reducer to be a safe and appropriate treatment for the reduction of weight.

"Properly admitted testimony of practicing physicians clearly establishes that Sekov Reducer is not a remedy for obesity; that it will not, as claimed, reduce the figure of a stout woman to the slender proportions shown in the picture on the container; that directions for use of the product were inadequate; and that its use is dangerous to health when used with the frequency or duration prescribed in the directions on the label, 'and this is true whether the patient is or is not suffering from hyperthyroidism of from hypothyroidism.'

"(1) Appellant Sekov Corporation contends that the fact that it had been previously proceeded against by the Federal Trade Commission barred inquiry by the District Court into the questions presented by the Government's libel. There is no merit in this contention. The issues in that proceeding were not identical with those here presented. Moreover, the power and duty of the District

Court to condemn the misbranded articles was not impaired or diminished by the former proceeding. United States v. Research Laboratories, 9 Cir., 126 F. 2d 42, 45.

"(2) The findings of the District Court are supported by the evidence and its judgment is in accordance with the applicable law.

"The judgment is affirmed."

On January 27, 1943, the case instituted in the District of Nevada and the other action at Houston, Tex., having been consolidated and removed to the District Court for the Northern District of California, and the claim and answer of the Sekov Corporation having been withdrawn, judgments of condemnation and forfeiture were entered and it was ordered that the clerk return the files to the respective districts, together with copies of the decrees of condemnation, forfeiture, and destruction, in order that the marshals for those districts might destroy the product. In April 1944, a decree was entered ordering that the product at Houston, Tex., be destroyed.

1003. Adulteration and misbranding of Nelson's Antacid Powder and misbranding of B-M Cold Caps and Fero-Tona. U. S. v. 30½ Dozen Vials of B-M Cold Caps, 12½ Dozen Bottles of Fero-Tona, and 17 Packages of Nelson's Antacid Powder. Default decrees of condemnation and destruction. (F. D. C. No. 9593. Sample Nos. 6597–F to 6599–F, incl.)

On March 22, 1943, the United States attorney for the Eastern District of Missouri filed libels against 30½ dozen vials of B–M Cold Caps, 12½ dozen bottles of Fero-Tona, and 17 packages of Nelson's Antacid Powder at St. Louis, Mo., alleging that the articles had been shipped in interstate commerce, from Cleveland, Ohio, by the Great Lakes Laboratories, on or about May 25 and November 6, 1942, and January 2, 1943; and charging that they were misbranded and that the Antacid Powder was also adulterated. The Cold Caps and the Fero-Tona were labeled in part: "Distributed by Ber-Mel [or "Mels"], Inc. Cleveland, Ohio."

Examination of the Cold Caps showed that they consisted essentially of acetanilid 1.72 grains and aspirin 4.47 grains per capsule, together with caffein, laxative plant drugs, including aloin, capsicum, and alkaloids extracted from belladonna. The product was alleged to be misbranded (1) in that it was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling, "One capsule every 2 or 3 hours with a glassful or more of water," since, when taken in such manner, it supplied a quantity of acetanilid which was dangerous to health; (2) in that the statement in its labeling, "For Temporary Relief of Minor Colds, Flu," was false and misleading since it would not afford temporary relief from flu or all the symptoms of minor colds; (3) in that it was fabricated from two or more ingredients and its label failed to bear a statement of the quantity or proportion of atropine, hyoscine, or hyoscyamine contained therein; (4) in that its labeling failed to bear adequate directions for use, since the directions which appeared upon the label provided for the administration of excessive amounts of acetanilid, and were therefore not adequate; and (5) in that its labeling failed to warn that frequent and continued use of a preparation containing acetanilid might be dangerous, causing serious blood disturbances, anemia, collapse, or dependence upon drugs, that frequent or continued use of a preparation containing belladonna alkaloids should be avoided, that the article was to be used cautiously if dryness of the throat occurred, and its use discontinued if rapid pulse or blurring of vision occurred, and that frequent or continued use of a laxative might result in dependence on laxatives.

Examination of the Fero-Tona showed that it consisted essentially of hexamethylenamine, potassium iodide, ferric chloride, laxative plant drugs, and strychnine sulfate. The bottle was contained in a carton much larger than necessary, since the bottle was surrounded by a liner occupying 11.8 percent of the volume of the carton, and there was 1½ inch head space above the bottle. It was alleged to be misbranded (1) in that the statements appearing in its labeling which represented and suggested that it was effective as a diuretic and was effective to aid important organs of the body to function properly were false and misleading since the article was not so effective; (2) in that its labeling failed to bear adequate directions for use, since the directions which appeared in the labeling provided for the continuous administration of a laxative and recommended for children the use of a preparation containing strychnine, and were therefore not adequate; and (3) in that its labeling failed to warn that a laxative should not be taken in case of nausea, vomiting, abdominal pain, or other symptoms of appendicitis, that frequent or contained use might result in dependence upon

a laxative, that an article containing potassium iodide should not be used in case of goiter except upon the advice of a physician, that its use should be discontinued if a skin rash appears, that no more than the recommended dose of a preparation containing strychnine should be taken, that frequent or continued use should be avoided, and that its use for children and elderly persons might be especially dangerous. It was alleged to be misbranded further in that its container was so made and filled as to be misleading, since the carton was much larger than necessary for the size of the bottle.

Examination showed that the Antacid Powder consisted essentially of compounds of sodium, calcium, and magnesium, including carbonate, and that it did not contain bismuth compounds. It was alleged to be adulterated in that its strength differed from that which it purported and was represented on its label to possess, "Bismuth Salts in the form of Carbonates Subnitrates." It was alleged to be misbranded in that the following statements appearing in its labeling, "Bismuth Salts in the form of Carbonates Subnitrates are widely prescribed for gastric ulcer, gastralgia, gastritis, hyperacidity, acidosis, etc. They form a soothing, protective coating over the highly inflamed mucous membranes of the stomach; mildly astringent and sedative. Carica Papaya * * * converts all protein foods such as meats and albumens into soluble and readily absorbed peptones. Malt Diastase Converts all starchy foods into soluble dextrins and sugars. Alkalinizer * * * Acidosis, * * * Functional Stomach Disorders * * * Gastric Ulcer, Gastritis, Gastralgia, Indigestion. This preparation is built up on strictly scientific principles, offers a rational and effective method of re-establishing the normal alkalinity of the body fluids without the danger of systemic disturbance. * * * instantly neutralize all stomach acids * * * instant relief from acidity and gas pressure," were false and misleading since such statements represented and suggested that the article contained bismuth salts and was effective in the treatment of the conditions and symptoms described and stated, whereas the article did not contain bismuth salts and was not effective in the treatment of those conditions and symptoms. It was alleged to be misbranded further in that it was in package form and its label failed to bear an accurate statement of the quantity of its contents.

On April 17, 1943, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

1004. Misbranding of Stero-Uteroids. U. S. v. 5 Cartons of Stero-Uteroids. Default decree of condemnation and destruction, with provision for the release of a portion of the product to the Food and Drug Administration. (F. D. C. No. 9546. Sample No. 37824–F.)

On or about March 24, 1943, the United States attorney for the Northern District of Illinois filed a libel against 5 cartons, each containing 2 tubes, of Stero-Uteroids at Chicago, Ill., alleging that the article had been shipped in interstate commerce by Charles A. Ainsworth, of Ainsworth Specialty Co., from Kansas City, Mo., within the period from on or about July 24, 1941, to October 17, 1942; and charging that it was misbranded.

Analysis showed that the article consisted essentially of small proportions of zinc sulfate, plant material (including alkaloid-bearing drugs), and a trace of iodine incorporated in a base of ichthammol and wool fat.

It was alleged to be misbranded in that it would be dangerous to health when used in the dosage and with the frequency prescribed, recommended, and suggested in the labeling, in that the name of the article, "Stero-Uteroids," and the directions, "Apply with catheter under aseptic conditions," which appeared in the labeling of some of the packages, represented and suggested the introduction of the article into the uterus, whereas the article, when introduced into the uterus was dangerous to health. It was alleged to be misbranded further in that the statement, "Stero-Uteroids," appearing on all the packages, and "Directions: Apply with catheter under aseptic conditions. For administration by physician only," appearing on some of the packages, were misleading since the statements represented and suggested that the article was a safe medicament for introduction into the uterus, whereas it was not a safe medicament, and its label failed to reveal the material fact that if so introduced it would endanger health and life.

On May 8, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed. On June 30, 1943, an amended order was entered which provided for the release of a portion of the product to the Food and Drug Administration.

1005. Misbranding of Pro-Nausea. U. S. v. 34 Bottles of Pro-Nausea. Decrees of condemnation and destruction. (F. D. C. No. 9553. Sample No. 35117-F.)

On March 29, 1943, the United States attorney for the Middle District of Alabama filed a libel against 34 bottles of Pro-Nausea at Phenix City, Ala., alleging that the article has been shipped in interstate commerce on or about January 28, 1943, from Griffin, Ga., by Dr. Thomas D. Thurmond; and charging that it was misbranded in violation of Sections 502 (a), 502 (e) (2), and 502 (j) of the Federal Food, Drug, and Cosmetic Act.

Examination showed that the article consisted essentially of sodium bromide, 110 grains per fluid ounce, and water.

The foregoing misbranding charges were based on the following recommendations made by the Federal Security Agency: Section 502 (j), that the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling, "Dose for Adult:—One table spoonful. Take one table spoonful of water after each dose. PRO-NAUSEA Relieves Vomiting During Pregnancy. Dose:—One table spoonful 30 minutes before meals. Take one table spoonful of water after each dose," since such directions provided for the taking of an excessive quantity of sodium bromide; Section 502 (a), that the following statements appearing on the label: "PRO-NAUSEA * * * Nonpoisonous Remedy for Sick Stomach Sick Headache Sea Sickness Nausea Following X-Ray Treatment * * * PRO-NAUSEA Relieves Vomiting During Pregnancy," were false and misleading since such statements represented and suggested that the article was a safe and effective treatment for the conditions described, whereas it was not a safe and effective treatment for such conditions, and was a dangerous drug; and Section 502 (e) (2), that it was fabricated from two or more ingredients and its label failed to bear a statement of the quantity or proportion of sodium bromide contained therein.

On June 28, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

1006. Action to enjoin and restrain interstate shipments of Mrs. Price's Specially Prepared Package of Boric Acid. U. S. v. Metta T. Price (Price Compound Co.) Permanent injunction granted. (Inj. No. 57.)

On June 21, 1943, the United States attorney for the District of Minnesota filed a complaint for the purpose of enjoining Metta T. Price, doing business as the Price Compound Co., Minneapolis, Minn., from the sale and distribution of chemical preservatives offered for use in home canning and food preservation, alleging, among other things:

That, since about the year 1937, the defendant had been engaged in the sale and distribution in interstate commerce of a product known as "Mrs. Price's Specially Prepared Package of Boric Acid," which upon examination was found to consist of 100 percent boric acid.

That, commencing on or about September 23, 1942, and again about the middle of May 1943, the product was the subject of numerous libel actions in various Federal judicial districts throughout the United States, and that the article so shipped was misbranded (1) in that the statements in the labeling which represented, suggested, and engendered the impression in the minds of the readers that the product, when used as directed in the canning of vegetables, fruits, pickles, and preserves, was safe and appropriate for such use, and would effect proper sterilization, conservation, and preservation of home-canned foods, were false and misleading, since it was potentially dangerous to the health of the consumer and would not insure proper sterilization, conservation, and preservation of home-canned foods; (2) the statements in the labeling admonishing the home canner to sterilize jars, and particularly the rubber rings, by boiling for 15 to 20 minutes were misleading, since these directions for sterilization are inadequate where heat-resistant, spore-forming bacteria are present; (3) in that the statement in the labeling, "Wash thoroughly as the most dangerous and the most difficult bacteria to destroy are in the soil," was misleading, since it represented and suggested that the thorough washing of vegetables would eliminate the most dangerous and difficult bacteria to destroy, whereas such washing would not insure that effect; (4) in that the statements in the labeling, "If the foregoing directions are followed and you have used good, fresh vegetables or fruits and the amount of compound directed, you will have no trouble in securing the best

*See also Nos. 1002, 1003.

results. You may ask why we are so particular to have the cans perfectly tight. The reason is that we wish you to do all you can mechanically to keep the goods, and then by the use of the compound, get a perfect result that neither one alone would secure," were false and misleading in that they represented and suggested that the use of the article according to directions would assure the perfect and best results in home canning, whereas the perfect and best results cannot be obtained by such use, since heat-resistant, spore-forming bacteria, capable of producing spoilage and toxins dangerous to health, would not be destroyed; and, (5) in that its labeling failed to bear adequate directions for use.

On June 28, 1943, the court entered its findings of fact and conclusions of law and order for permanent injunction, and on the same date judgment was entered enjoining the defendant, her employees, agents, distributors, attorneys, assigns, and any and all persons acting in concert with her, from introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce, of Mrs. Price's Specially Prepared Package of Boric Acid, or any similar article containing boric acid for any purpose in violation of the Federal Food, Drug and Cosmetic Act.

The product was also alleged to be misbranded under the provisions of the law applicable to foods, reported in food notices of judgment No. 5759, in which also appear the court's findings of fact and conclusions of law with respect to the product and two other products, Mrs. Price's Compound and Price's No-Ice.

1007. Misbranding of Chu-man-ic's Regular "Triple XXX" Herb and Iron Mensal Medicine. U. S. v. Charles Roehm (Chumanic Medicine Co.). Plea of not guilty. Tried to a jury. Verdict of guilty. Sentence of 6 months in jail suspended and defendant placed on probation for 1 year. (F. D. C. No. 7723. Sample No. 59725–E.)

On December 10, 1942, the United States attorney for the Eastern District of Michigan filed an information against Charles Roehm, trading as the Chumanie Medicine Co. at New Richmond, Ohio, and Detroit, Mich., alleging shipment on or about January 12, 1942, from the State of Michigan into the State of Maryland of a quantity of the above-named product.

Analysis of the article showed that it was in the form of tablets which contained ferrous sulfate and plant material, including aloe.

The article was alleged to be misbranded in that the statements in its labeling which represented and suggested that it would be efficacious as a mensal medicine, and would be efficacious in the treatment of amenorrhea (suppressed menstruation), oligomenorrhea (scanty or infrequent menstruation), and dysmenorrhea (difficult or painful menstruation), were false and misleading since the article would not be so efficacious. It was alleged to be misbranded further in that its labeling did not bear adequate directions for use, since it was a laxative and should not be used continuously, and the labeling failed to warn against continuous use of the article.

On December 7, 1943, the case came on for trial, and at its conclusion on December 9, 1943, the jury returned a verdict of guilty. The court imposed a sentence of 6 months in jail, but suspended the sentence and placed the defendant on probation for 1 year, specifying as a part of the probation that he was not to prepare or market the above-named product until he had submitted an acceptable label to the Food and Drug Administration.

1008. Misbranding of Dye's Compound Tablets and Dye's Laxative Pellets. U. S. v. Clara A. Skey (Dr. J. H. Dye Medical Co.). Plea of nolo contendere. Fine, $150. (F. D. C. No. 6456. Sample Nos. 7673–E, 7674–E, 11173–E, 11174–E.)

On May 25, 1942, the United States attorney for the Western District of New York filed an information against Clara A. Skey, trading as the Dr. J. H. Dye Medical Co., Buffalo, N. Y., alleging shipment on or about January 17, and March 12 and 31, 1941, from the State of New York into the States of California and Texas of quantities of the above-named products which were misbranded.

Analyses showed that Dye's Compound Tablets consisted essentially of extracts of plant drugs including black haw and an alkaloid-bearing drug, and that Dye's Laxative Pellets consisted essentially of extracts of plant drugs including aloin, podophyllin, and Hydrastis.

The Dye's Compound Tablets were alleged to be misbranded in that the statements appearing in their labeling which represented and suggested that they would be efficacious in reducing the distressing symtoms of functional dysmenorrhea; that they would help build up physical resistance and tend to reduce minor nervous conditions due to functional painful menstruation; that they would be efficacious to increase the appetite and resistance; that they would be efficacious in

the alleviation of painful symptoms of certain female functional irregularities, and were particularly indicated for this purpose for the woman of mature age; that they would be efficacious in reducing the annoying and sometimes painful symptoms of change of life; that they would be efficacious in the treatment of headache or general nervousness during menstrual periods; that they would aid the digestion and strengthen the young woman at the time of puberty; that they would be efficacious in the treatment of nervous irritability, headache, backache, nausea, debility, and rings under the eyes; that they would give the young mother more appetite and assist her in obtaining more nourishment from the food eaten, and alleviate nervousness and weakness, and the tendency to tire easily; that they would be efficacious to bring the joy of motherhood to women; that they would be efficacious in the treatment of irritability, nervousness, melancholia, hysteria, loss of sleep, and peculiar pains in various parts of the body during or preceding change of life; that they would be efficacious in the cure, mitigation, treatment, or prevention of amenorrhea (absence of the menstrual periods or scantiness of the flow for no apparent reason), dysmenorrhea (difficult or painful menstruation), menorrhagia (excessive or abundant menstruation), metritis (inflammation of the matrix), and ovaritis (inflammation of the ovaries); that they would be efficacious to make women more attractive; and that they would develop personal magnetism, prevent loss of vitality, and bring about a feeling of vigor and animation, were false and misleading since the tables were not efficacious for such purposes and would not accomplish the results claimed.

The Laxative Pellets were alleged to be misbranded (1) in that the statements appearing in their labeling which represented and suggested that they would be efficacious in relieving headaches, coated tongue, bad breath, aggravated pimply skin, lassitude, and indigestion were false and misleading since the tablets would not be efficacious in relieving such conditions; (2) in that their labeling did not bear adequate directions for use, since the directions for use displayed in the labeling were indefinite and did not limit the duration of use of the tablets; and, (3) in that the labeling did not bear such adequate warnings against use in those pathological conditions wherein their use might be dangerous to health, or against unsafe duration of administration, in such manner and form as are necessary for the protection of users, since the tablets were a laxative and their labeling did not bear a warning that they should not be used when the symptoms of appendicitis, such as nausea, vomiting, and abdominal pain, were present, and that frequent or continued use of the tablets might result in dependence on laxatives.

On October 4, 1943, the defendant entered a plea of nolo contendere, and on October 25, 1943, the court imposed a fine of $150.

1009. Misbranding of McMillan's Nomoppin and Demytin, and adulteration and misbranding of effervescent solution of citrate of magnesia. U. S. v. William Cicero McMillan (McMillan Drug Co.). Plea of guilty. Fine, $1. (F. D. C. Nos. 5486, 10584. Sample Nos. 254–E, 20499–E, 20925–E, 35609–F.)

The products "Nomoppin" and "Demytin" were misbranded because of false and misleading curative and therapeutic claims in the labeling, and the effervescent solution of citrate of magnesia was adulterated and misbranded because of failure to conform with the Pharmacopoeia requirements, and because the labeling failed to bear such adequate warnings as are necessary for the protection of users.

On September 9 and November 3, 1943, the United States attorney for the Eastern District of South Carolina filed two informations against William Cicero McMillan, trading as the McMillan Drug Co. at Columbia, S. C., alleging shipment within the period from on or about September 10 and 24, 1940, March 3, 1941, and August 24, 1943, from the State of South Carolina into the State of Georgia of quantities of McMillan's Nomoppin and McMillan's Demytin which were misbranded, and of a quantity of effervescent solution of citrate of magnesia which was adulterated and misbranded.

Analysis of a sample of the "Nomoppin" showed that it consisted essentially of potassium arsenite containing 2.01 grams of arsenic trioxide per 100 cc., and water. Analysis of samples of "Demytin" showed that it consisted essentially of calcium thiosulfate, calcium polysulfide, and water.

The Nomoppin was alleged to be misbranded in that representations on the bottle label and in the accompanying circular to the effect that it would be efficacious as a remedy, cure, or preventative for chicken sorehead (chicken pox); that it would be efficacious to aid egg production, hasten molting, and brighten plumage; that it would prevent loss of flesh and vigor from sorehead; that it was an internal remedy which would be efficacious in the treatment of sorehead with-

out the necessity of catching, greasing, and other local treatment; that it would protect little and big chicks from mites; and that it would increase egg production and improve the health of the flock so that more and stronger chicks would be raised were false and misleading since the article would not be efficacious to accomlish such purposes. It was alleged to be misbranded further in that it was in package form and did not bear a label containing an accurate statement of the quantity of the contents, since the label of the container bore no statement of the quantity of the contents; and in that its label did not bear the common or usual name of the article, potassium arsenite.

The Demytin was alleged to be misbranded in that representations on the bottle label and in the accompanying circular to the effect that it would increase egg yield by freeing hens from mites; that it would be efficacious in preventing diarrhea; that it would promote prompter molting, and induce an earlier return to laying conditions; that it would tend to brighten plumage; that it would protect little and big chicks from mites; that it would increase egg production and improve the health of the flock so that more and stronger chicks were raised; and that it would supply a ration ingredient which is often absent and which is required to produce the egg, build bone, strength, and vigor, were false and misleading since the article would not be efficacious for such purposes.

The solution of citrate of magnesia was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its strength differed from and its quality fell below the standard set forth in that compendium since the article contained, in each 100 cc., an amount of magnesium citrate corresponding to not more than 0.653 gram of magnesium oxide, and 10 cc. of the solution contained citric acid equivalent to not more than 13.1 cc. of half-normal hydrochloric acid, whereas the Pharmacopoeia provides that solution of magnesium citrate shall contain, in each 100 cc., an amount of magnesium citrate corresponding to not less than 1.6 gram of magnesium oxide, and that 10 cc. of the solution shall contain citric acid equivalent to not less than 26 cc. of half-normal hydrochloric acid.

The solution of citrate of magnesia was alleged to be misbranded in that its labeling did not bear adequate warnings against use in those pathological conditions wherein its use might be dangerous to health, since it was a cathartic or laxative drug and should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present, and a statement that frequent and continued use might result in dependence upon laxatives. It was alleged to be misbranded further in that it was in package form and did not bear a label containing an accurate statement of the quantity of the contents.

On November 3, 1943, the defendant having entered a plea of guilty, the court imposed a fine of $1, which was applicable to the 2 informations, with the understanding that the defendant immediately discontinue interstate business and discontinue business entirely on or before January 1, 1944.

1010. Misbranding of Iowa Worm Powder and Iowa Regulator for Hogs. U. S. v. Howard-Iowa Products Co. Demurrer to count 1 of the information filed and sustained. Pleas of guilty entered to remaining counts. Fine of $100 on each of 2 counts, together with costs. (F. D. C. No. 8734. Sample Nos. 94545–E, 94546–E.)

On January 8, 1943, the United States attorney for the Southern District of Iowa filed an information in 2 counts against the Howard-Iowa Products Co., a corporation, Jefferson, Iowa, alleging shipment on or about March 23, 1942, from the State of Iowa into the State of Illinois of a quantity of Iowa Worm Powder and Iowa Regulator for Hogs.

Analysis of the Iowa Worm Powder showed that it consisted essentially of sodium bicarbonate, compounds of calcium, magnesium, iron and aluminum, santonin, charcoal, and plant material, including flaxseed.

Count 1 of the information alleged that the Iowa Worm Powder was misbranded in that certain statements and designs borne on the carton containing the article, and certain statements in the circular enclosed in the carton were false and misleading since they represented and suggested that the article would be efficacious in the cure, mitigation, treatment, or prevention of all species of worms that infest hogs, and that it would correct unthriftiness in hogs resulting from all species of worms, whereas the article would not be efficacious for the purposes recommended.

Analysis of the Iowa Regulator for Hogs showed that it consisted essentially of sodium sulfate, sodium bicarbonate, sodium chloride, ammonium chloride, calcium carbonate, calcium phosphate, sulfur, a compound of iron, charcoal, and unidentified plant material.

It was alleged to be misbranded (count 2), because of false and misleading statements in its labeling which represented and suggested that it would be efficacious as a regulator for hogs; that it would be an effective aid in keeping hogs thrifty; that it would prevent indigestion and poisoning of the blood, and would cause the bowels to become normal; that it would be efficacious as a treatment for scours in young pigs; that it would clean the poison out of sows and correct the sow's milk; that it was an expectorant which would act upon the bronchial tubes and lungs; and that it would be efficacious in the treatment of colds and congestion of the lungs, would prevent pneumonia in hogs, and was an effective treatment for sick hogs that are thumping.

On May 22, 1943, the defendant pleaded guilty to count 2 of the information and entered a demurrer to count 1, and on May 29, 1943, an order was entered continuing the hearing on the demurrer and permitting the information to be amended by adding additional counts. An amended information was accordingly filed on August 30, 1943, in which was added a third count, alleging that the Iowa Worm Powder was misbranded further (1) in that the statements appearing in the aforesaid circular which represented and suggested that the Iowa Regulator would be efficacious as a regulator of the physiological functions of hogs, and that the Iowa Worm Powder and the Iowa Regulator, when used together, would be efficacious to relieve congestion of the lungs in hogs, were false and misleading, since the Iowa Regulator would not be efficacious as a regulator for any physiological function of hogs and the Iowa Worm Powder and the Iowa Regulator, whether used alone or together, would not be efficacious to relieve congestion of the lungs in hogs; (2) in that the worm powder was in package form and did not bear a label containing an accurate statement of the quantity of the contents; (3) in that it was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient; and (4) in that its labeling did not bear adequate directions for use, since the directions on the label did not state or indicate the quantity of the article to be administered to each hog or to a given number of hogs.

On September 11, 1943, the defendant having entered a plea of guilty to the third count of the information, the court proceeded with the hearing on the demurrer, and on October 13, 1943, handed down the following ruling sustaining the demurrer:

DEWEY, *District Judge:* "To an Amended and Substituted Information the defendant has filed a demurrer to Count 1, in effect, claiming that such count does not charge an offense against it.

"The charge is misbranding of drugs.

"The drugs complained of are labeled 'IOWA WORM POWDER FOR ASCARIS WORMS IN HOGS' and this statement appears on the outside of the package.

"Accompanying the package and inside thereof is a circular directing the use of the worm powder on hogs. The circular in its direction for use refers to 'the Worm Powder' as being 'the Iowa Worm Powder' and it is difficult to see how it refers to any other powder than that stated on the package as being 'Worm Powder for Ascaris Worms in Hogs.'

"The charge in Count 1 is that the label on the outside of the package showing two hogs, one thin and unthrifty and the other fat and thrifty looking, with the statement thereunder: 'Take Iowa Worm Powder and be Fat,' together with the directions for the use of the powder contained in the package, which does not specifically refer to Ascaris Worms in hogs, but only to 'the Worm Powder' and to the 'Iowa Worm Powder,' is false and misleading in this: 'that the said statements represented and suggested that said drug would be efficacious in the cure, mitigation, treatment or prevention of all species of worms that infest hogs.'

"Specifically, then, the charge is that the label on the outside of the package, together with the directions for the use of the worm powder, by suggestion and inference, states and represents that the worm powder would be efficacious in the cure of all worms that infest hogs instead of Ascaris Worms alone.

"The court raised the question as to whether the circular enclosed in a package should be considered on the question of misbranding, but the statement in the new act of 1938 that 'the term 'labeling' means all labels and other written, printed, or graphic matter * * * accompanying such article', and the case of Eckman's Alterative v. United States, 239 U. S. 510, definitely determine that the circular contained within the package is to be considered on the question of whether the labeling was a misbranding.

"However, I am unable to find anything in the label or in the statement enclosed in the package that indicates, let alone, suggests or states, that the Iowa

Worm Powder in the package was efficacious in the cure or mitigation of all worms in hogs.

"The label in large type expressly states that it is 'Worm Powder for Ascaris Worms in Hogs' and designates it as 'Iowa Worm Powder.' The directions for the use of the powder refers to either 'the Worm Powder,' which certainly means the Worm Powder contained in the package, or 'Iowa Worm Powder,' which even more definitely refers to the Worm Powder in the package, and the worm powder in the package is labeled as clearly and distinctly as it could be as a Worm Powder for Ascaris Worms without any suggestion or inference that it could be used or was efficacious in any manner or degree in destroying other worms in hogs.

"The defendant's demurrer to Count 1 of the Amended and Substituted Information is sustained and said Count is dismissed as not stating an offense against the defendant. The United States of America excepts. Signed at Des Moines, Iowa, this 13th day of October, 1943."

On November 30, 1943, no appeal having been noted with respect to the ruling on the demurrer, the court imposed a fine of $100 on each of counts 2 and 3, a total of $200, together with costs.

1011. Misbranding of Speagolax, Hunt's Salve, Triple-X Medicine, Booth's Balm, Booth's Pills, Liver-Cure, Fem-Re-Ills, Targosine, Jew David's or Hebrew Plaster, B. P. Stomach and Intestinal Corrective, Irogen, and Colonex Tablets; and adulteration and misbranding of Tansy. U. S. v. Allen Dobson and Matt H. Dobson, Jr. (Dobson & Co.). Pleas of nolo contendere. Fine, $150 against each defendant. (F. D. C. No. 8766. Sample Nos. 59789-E, 59791-E to 59797-E, incl., 59799-E, 78301-E, 78302-E.)

On February 18, 1943, the United States attorney for the Western District of North Carolina filed an information against Allen Dobson and Matt H. Dobson, Jr., trading as Dobson & Co., at Nashville, Tenn., and Rutherfordton, N. C., alleging shipment on or about April 16, 1942, from the State of North Carolina into the State of Virginia of quantities of the above-named products. The articles were labeled in part: "Speagolax * * * Put up and Guaranteed by Speagolax Medicine Co., Durham, N. C.," "Hunt's Salve * * * Manufactured by A. B. Richards Med. Co., Sherman, Texas," "Triple-X * * * Medicine * * * Triple X Laboratories Scotland Neck, N. C.," "Booth's Balm * * * [or "Booth's Pills"] * * * Booth's Hyomei Co., Ithaca, N. Y.," "Tansy * * * S. W. Gould & Bros. * * * Malden, Mass.," "Liver-Cure Munyon's Homeopathic Home Remedies," "Fem-Re-Ills * * * Guaranteed by the Henry S. Wampole Company * * * Baltimore, Maryland," "Targosine * * * Manufactured and Guaranteed by the Targosine Co. Monroe, N. C.," "Jew David's or Hebrew Plaster All Genuine Signed E. Taylor Right Secured Comstock & Co. Rochester, N. Y.," "B. P. Stomach and Intestinal Corrective Burwell & Dunn Co. * * * Charlotte, N. C.," "Irogen [or "Colonex Tablets"] * * * Guardian Health Products Co. Incorporated Atlanta, Georgia."

Analysis of the Speagolax showed that it was a brown liquid, having a bitter taste and consisting essentially of an iron salt, nux vomica extract, benzoates, cascara, iodides, alcohol, sugar, and water. It was alleged to be misbranded because of false and misleading statements in its labeling which represented and suggested that the article would be efficacious as a tonic for the stomach and blood; that it would be efficacious in the cure, mitigation, treatment, or prevention of rheumatism, lumbago, indigestion, liver and kidney trouble, and diseases due to impure blood; and that it would aid digestion and restore tone to a run-down system. It was alleged to be misbranded further (1) in that its labeling failed to bear adequate directions for use, since the directions on the label, "Dose:—One tablespoonful three times a day before meals," suggested that the article should be used continuously, whereas it was a laxative and should not be used continuously, and the direction, "Children according to age," was not explicit, whereas directions should be explicit; (2) in that its labeling failed to bear adequate warnings against use in those pathological conditions wherein its use might be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form as are necessary for the protection of users, since the article contained a laxative, cascara, and its labeling did not warn that it should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present, and that frequent or continued use might result in dependence upon laxatives; and (3) in that its container was so made, formed, or filled as to be misleading since the container was larger than was necessary to contain the article.

Analysis of the Hunt's Salve showed that it was a greenish-brown ointment consisting essentially of sulfur, oil of sassafras, a mercury salt present as a

sulfide, and resins incorporated in a petrolatum base, together with small amounts of phenol, iodides, and chrysarobin. It was alleged to be misbranded in that the statements in its labeling which represented and suggested that it would be efficacious in the cure, mitigation, treatment, or prevention of itch, 7-year itch, barber's itch, itch in all of its various forms, eczema, scald head, piles, old sores, boils and all skin diseases, including skin diseases of babies and small children, were false and misleading since the product would not be efficacious for such purposes. It was alleged to be misbranded further in that it was not designated solely by a name recognized in an official compendium, and it was fabricated from two or more ingredients, one of which was a mercury salt, and the labeling failed to bear the common or usual name of each active ingredient, including a statement of the quantity or proportion of the mercury salt contained in the article.

Analysis of the Triple-X Medicine showed that it was a brown-colored emulsion of copaiba and cubeb oils and a sugar solution, emulsified with a water-soluble gum. It was alleged to be misbranded because of false and misleading statements in its labeling which represented and suggested that it would be efficacious in the cure, mitigation, treatment, or prevention of acute and chronic discharges. It was alleged to be misbranded further in that it was not designated solely by a name recognized in an official compendium, and in that it was fabricated from two or more ingredients and its label failed to bear the common or usual name of each active ingredient.

Analysis of the Booth's Balm showed that it was a green ointment consisting of chlorophyll containing plant extractives, a cresol-like substance, and a trace of eucalyptol, all incorporated in a base of petrolatum and fatty material. It was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that the article would be efficacious in the cure, mitigation, treatment, or prevention of many forms of skin diseases, such as dandruff, scalp irritation, pimples, blackheads, eczema, and itching skin; that it would be efficacious in the cure, mitigation, treatment, or prevention of bronchial catarrh, head colds, spasmodic croup, aching and tender feet, tender breasts, and sore nipples; and that it would be beneficial during pregnancy, were false and misleading since the article would not be efficacious or beneficial for such purposes.

Analysis of the Booth's Pills showed that they contained emodin-bearing drugs, apparently aloes.

The article was alleged to be misbranded in that its labeling failed to bear adequate warnings against use in those pathological conditions wherein its use might be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form as are necessary for the protection of users, since the article contained aloes, a laxative drug, and its labeling did not bear a warning that it should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present, and that frequent or continued use might result in dependence on laxatives.

Analysis of Tansy showed that it consisted of dried plant material containing the leaves and flower heads of the tansy plant. It was alleged to be adulterated in that it consisted in whole or in part of a filthy substance by reason of the presence therein of insects, insect fragments, and insect excreta, and because of fire or water damage. It was alleged to be misbranded because of false and misleading statements in its labeling which represented and suggested that the article would be efficacious as a tonic, emmenagogue, and anthelmintic; and that it would be efficacious in the cure, mitigation, treatment, or prevention of amenorrhea and hysteria.

Analysis of the Liver-Cure showed that it consisted of small spherical sugar pellets with no other ingredient detected. It was alleged to be misbranded in that the statements in its labeling which represented and suggested that it would be efficacious in the cure, mitigation, treatment, or prevention of jaundice, and all diseases of the liver, including torpid liver, and all acute congested conditions of the liver, biliousness, constipation, bilious headache, and sick headache; and that it would be efficacious to relieve bad taste in the mouth, coated tongue, worn-out feeling, highly colored urine, soreness in the right side, dull spirits, and restless nights, were false and misleading since it would not be efficacious for such purposes.

Analysis of the Fem-Re-Ills showed that it was a white, sugar-coated elliptical pill, consisting essentially of ferrous sulfate, calcium carbonate, oil of savin, plant extractives including aloes, and sugar, together with small amounts of ergot alkaloids. It was alleged to be misbranded in that the statements appear-

ing in its labeling which represented and suggested that it would be efficacious as an ideal remedy for amenorrhea, dysmenorrhea, and menstrual disorders; that it would be efficacious in the cure, mitigation, treatment, or prevention of functional derangement of the reproductive organisms; that it would assist nature in its efforts to re-establish the menstrual flow at the regular period; and that it would prevent difficult, painful, over-profuse, and other morbid menstrual conditions, and would keep those important functions normal, were false and misleading, since it would not be efficacious for such purposes. It was alleged to be misbranded further in that it was not designated solely by a name recognized in an official compendium; and that it was fabricated from two or more ingredients and its label failed to bear the common or usual name of each active ingredient.

Analysis of the Targosine showed that it consisted essentially of turpentine, kerosene, fatty material, a water-soluble gum, and water, together with a small amount of chloroform. It was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that it would be efficacious as an instant relief for eczema, old sores, skin diseases, burns, scalds, and sunburn; that it would be efficacious in the cure, mitigation, treatment, or prevention of pains in the back, stiff neck, rheumatic pains, soreness in the chest, colds, croup, tonsilitis, sore throat, poison oak, itch, barber's itch, eczema, boils, old sores, ulcers, eruptions, pimples, vaccination sores, breastcake, and sore nipples, were false and misleading since it would not be efficacious for such purposes. It was alleged to be misbranded further in that it was not designated solely by a name recognized in an official compendium, and in that it was fabricated from two or more ingredients and its label failed to bear the common or usual name of each active ingredient.

Analysis of the Jew David's or Hebrew Plaster showed it to be a brown, translucent and somewhat plastic mass having an agreeable terebinthinate odor, the odor, appearance, and physical properties resembling the oleoresin, Burgundy pitch. It was alleged to be misbranded because of false and misleading statements in its labeling which represented and suggested that the article would be efficacious in the cure, mitigation, treatment, or prevention of local inflammation, scrofulous affections, gout, inflammatory and chronic rheumatism, and lung and liver affections; and that it would be beneficial in cases of weakness, such as weakness and pain in the stomach and affections of the spine.

Analysis of the B. P. Stomach and Intestinal Corrective showed that it was a viscous mixture containing suspended solid material and a brown liquid, with a mint odor and taste, consisting essentially of bismuth subsalicylate together with a small amount of volatile oils including peppermint, sugar, and water.

It was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that would be efficacious as an antiferment: that it would be efficacious for and would correct fermentation arising from improperly prepared and infected food; and that it would be efficacious in the cure, mitigation, treatment, and prevention of vomiting, diarrhea, dysentery, flux, and cholera morbus in children and adults were false and misleading since it would not be efficacious for such purposes. It was alleged to be misbranded further in that it was not designated solely by a name recognized in an official compendium; and in that it was fabricated from two or more ingredients and its labeling failed to bear the common or usual name of each active ingredient.

Analysis of the Irogen showed that it was a dark brown liquid containing considerable sediment and consisting essentially of alcohol, an iron salt, malt, manganese salt, cinchona alkaloids, nux vomica alkaloids, wild cherry, emodin-bearing drugs, phosphorus compounds, a sodium salt, sugar, and water. It was alleged to be misbranded because of the false and misleading statements in its labeling which represented and suggested that the article would be efficacious as a prompt aid for enriching the blood; that it would be efficacious in building up bodily strength and restoring impaired tissues; and that it would aid digestion and restore tone to the system. It was alleged to be misbranded further in that it was not designated solely by a name recognized in an official compendium; and in that it was fabricated from two or more ingredients, including the ingredient strychnine, and its labeling failed to bear the common or usual name of each active ingredient, including the quantity or proportion of strychnine contained in the article.

Analysis of the Colonex Tablets showed that the article consisted of sugar-coated tablets containing phenolphthalein and emodin drugs. It was alleged to be misbranded because of false and misleading statements in its labeling which represented and suggested that the article would be efficacious as a stimulator

of the liver cells; that it would improve digestion and assimilation; and that it would be efficacious in the prevention of premature old age, rheumatism, high blood pressure, Bright's disease, diabetes, and constant headaches, and would produce normal bowel movements. It was alleged to be misbranded further in that its labeling failed to bear adequate directions for use since the directions suggested continuous use of the article, whereas laxative preparations should not be used continuously, and the directions were not explicit with respect to the dosage for children; and in that its labeling failed to bear such adequate warnings against use in those pathological conditions wherein its use might be dangerous to health, or against unsafe dosages or methods or duration of administration, in such manner and form as are necessary for the protection of users, since the article contained laxatives, phenolphthalein and emodin-bearing drugs, and its labeling failed to bear a warning that they should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present, and it did not bear a warning that frequent or continued use might result in dependence upon laxatives.

On November 8, 1943, the defendants having entered pleas of nolo contendere, the court imposed a fine of $150 against each defendant.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

1012. Adulteration and misbranding of salicylate soda, strychnine sulfate, Rheumatic No. 3, phenobarbital tablets, and acetanilid, caffeine and sodium salicylate compound tablets. U. S. v. Charles Killgore Co., Inc. Plea of guilty. Fine, $1,000. (F. D. C. No. 7659. Sample Nos. 84880–E, 84881–E, 84943–E, 84944–E, 90441–E.)

The Rheumatic No. 3 Tablets and the acetanilid, caffeine and sodium salicylate compound tablets differed from their own declared standards of strength and quality. The remainder of the products were sold under names recognized in the National Formulary and differed in strength from the standards prescribed in that compendium.

On April 5, 1943, the United States attorney for the Southern District of New York filed an information against the Charles Killgore Co., Inc., Yonkers, N. Y., alleging shipments on September 8 and December 1 and 4, 1941, from the State of New York into the States of Connecticut, New Jersey, and Rhode Island of quantities of the above-named drugs which were adulterated and misbranded.

The salicylate soda tablets were alleged to be adulterated in that they purported to be and were represented as a drug the name of which is recognized in the National Formulary, but their strength differed from the standard set forth in that compendium since each tablet contained the equivalent of not more than 89 percent of the labeled amount of sodium salicylate, whereas the National Formulary provides that tablets of sodium salicylate shall contain not less than 91 percent of the labeled amount; and their difference in strength from the standard was not plainly stated on the label. They were alleged to be misbranded in that the statement "Salicylate Soda 5 grains," appearing on the label, was false and misleading.

The strychnine sulfate tablets were alleged to be adulterated in that they purported to be and were represented as a drug the name of which, tablets of strychnine sulfate, is recognized in the National Formulary, but their strength differed from the standard set forth in that compendium since each tablet contained the equivalent of not more than 79.2 percent of the labeled amount of strychnine sulfate, whereas the National Formularly provides that tablets of strychnine sulfate of this size shall contain not less than 91 percent of the labeled amount of strychnine sulfate; and their difference in strength from the standard was not plainly stated on their label. They were alleged to be misbranded in that the statement "Strychnine Sulph 1–30 gr.," appearing on the label, was false and misleading.

The Rheumatic No. 3 Tablets were alleged to be adulterated in that their strength differed from and their quality fell below that which they purported and were represented to possess, since each tablet was represented to contain 7½ grains of soda salicylate, i. e., sodium salicylate, whereas each tablet contained not more than 6.18 grains of sodium salicylate. They were alleged to be misbranded in that the statement "Soda Salicylate 7½ grs.," appearing on the label, was false and misleading.

The phenobarbital tablets were alleged to be adulterated in that they purported to be and were represented as a drug the name of which is recognized in the

*See also Nos. 1002, 1003.

National Formulary, but their strength differed from the standard set forth in that compendium, since each table contained the equivalent of not more than 85.1 percent of the labeled amount of phenobarbital, whereas the National Formulary provides that tablets of phenobarbital of this size shall contain not less than 92.5 percent of the labeled amount of phenobarbital; and their difference in strength from the standard was not plainly stated on the label. They were alleged to be misbranded in that the statement "Phenobarbital 1½ gr.," appearing on the label, was false and misleading.

The acetanilid, caffeine and sodium salicylate compound tablets were alleged to be adulterated in that their strength differed from and their quality fell below that which they purported and were represented to possess, since each tablet was represented to contain 2½ grains of acetanilid and 1¾ grains of sodium salicylate, whereas each tablet contained not more than 2.22 grains of acetanilid and not more than 1.19 grains of sodium salicylate. They were alleged to be misbranded in that the statement, "Acetanilid 2 1–2 grs. * * * Sodium Salicylate 1, 3–4 grs.," appearing on the label, was false and misleading.

On May 28, 1943, the defendant having changed his original plea of not guilty to a plea of guilty, the court imposed a fine of $1,000.

1013. Adulteration and misbranding of Sun-Glow Cod Liver Oil Concentrate Tablets. U. S. v. Brewer & Co., Inc. Plea of guilty. Fine, $150. (F. D. C. No. 7306. Sample No. 75736–E.)

On October 8, 1942, the United States attorney for the District of Massachusetts filed an information against Brewer & Co., Inc., Worcester, Mass., alleging shipment on or about July 15, 1941, from the State of Massachusetts into the State of Maine of a quantity of the above-named product.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess, since it purported and was represented to contain not less than 3,140 U. S. P. XI units of vitamin A and not less than 314 U. S. P. XI units of vitamin D per tablet, whereas it contained not more than 2,740 U. S. P. XI units of vitamin A and not more than 235 U. S. P. XI units of vitamin D per tablet. It was alleged to be misbranded in that the statements in its labeling, "Each tablet contains not less than 3140 U. S. P. XI units Vitamin A and 314 units Vitamin D," and "These tablets are biologically standardized to contain not less than 3140 U. S. P. XI units Vitamin A and 314 U. S. P. XI units Vitamin D per tablet. * * *," were false and misleading; and in that the statements in its labeling which represented and suggested that it would be efficacious in the prevention and treatment of disease in man by increasing general resistance and toning the system, and that it would develop strong bones and good teeth, were false and misleading since it would not be efficacious for such purposes.

The article was also alleged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in the notices of judgment on foods.

On October 5, 1943, the defendant having entered a plea of guilty, the court imposed a fine of $150.

1014. Adulteration and misbranding of Analgesic Tablets, boric acid compound ointment, Boro-Oxyquinoline Compound Vaginal Suppositories, aspirin tablets, and Eye Unguent, and misbranding of Hexamide Compound No. 1. U. S. v. McDonald Pharmacal Co., Inc., and Edmund L. McDonald. Pleas of guilty. Fines, $50. (F. D. C. No. 8758. Sample Nos. 76713–E, 76714–E, 76735–E, 76890–E, 76893–E, 76928–E.)

The aspirin tablets differed from the requirements of the National Formulary; the Hexamide Compound No. 1 bore on its labeling false and misleading therapeutic claims; and the remaining products differed from their declared standards.

On April 6, 1943, the United States attorney for the District of Minnesota filed an information against the McDonald Pharmacal Co., Inc., St. Paul, Minn., and Edmund L. McDonald, alleging shipment within the period from on or about December 10, 1941, to on or about April 15, 1942, from the State of Minnesota into the State of South Dakota of a quantity of Hexamide Compound No. 1 which was misbranded, and into the State of Iowa of a quantity of Boro-Oxyquinoline Compound Vaginal Suppositories, and into the State of Wisconsin of quantities of the other above-named products which were adulterated and misbranded.

Adulteration of the Analgesic Tablets was alleged in that their strength differed from and their quality fell below that which they were represented to possess since they were represented to contain in each tablet 3 grains of aspirin, 2 grains of acetphenetidin, and ½ grain of caffeine citrate, whereas they contained in each tablet not more than 2.38 grains of aspirin, not more than 1.60 grains of acetphenetidin, and not more than 0.40 grain of caffeine citrate. They

were alleged to be misbranded in that the statements, "Aspirin 3 grs., Acetphenetidin 2 grs., Caffeine Citrate ½ grs.," borne on the label, were false and misleading.

Adulteration of the boric acid compound ointment was alleged in that its strength differed from and its quality fell below that which it was represented to possess since it was represented to be an antiseptic, whereas it was not. It was alleged to be misbranded in that the statement "An excellent antiseptic," borne on the label, was false and misleading.

The Boro-Oxyquinoline Compound Vaginal Suppositories were alleged to be adulterated in that their strength differed from that which they were represented to possess since they were represented to contain 2 grains of quinine sulfate, whereas they contained not more than 1.44 grains of quinine sulfate. They were alleged to be misbranded in that the statement "Quinine Sulphate 2 gr.," borne on the label, was false and misleading.

The Eye Unguent was alleged to be adulterated in that its strength differed from that which it was represented to possess since it was represented to contain 2 percent of yellow oxide of mercury, whereas it contained not less than 2.3 percent of yellow oxide of mercury. It was alleged to be misbranded in that the statement "Yellow Oxide Mercury 2%," borne on its label, was false and misleading.

The aspirin tablets were alleged to be adulterated in that they purported to be and were represented as a drug the names of which, tablets of acetylsalicylic acid and aspirin tablets, are recognized in the National Formulary, an official compendium, but their strength differed from the standard set forth in that compendium since each tablet contained the equivalent of not more than 85.6 percent of the labeled amount of acetylsalicylic acid, whereas the National Formulary provides that tablets of acetylsalicylic acid or aspirin tablets shall contain not less than 92.5 percent of the labeled amount of acetylsalicylic acid; and their difference in strength from such standard was not plainly stated on the label. They were alleged to be misbranded in that the statement "Aspirin Acid Acetylsalicylic 5 Grains," borne on the label, was false and misleading.

Analysis of a sample of the Hexamide Compound No. 1 showed that it consisted essentially of salol, methenamine, small proportions of benzoic acid and methylene blue, and not more than 0.012 grain of sulfanilamide per tablet. It was alleged to be misbranded in that the statements, "(Formerly Cystitis) * * * Recommended in the treatment of Cystitis and Gonorrhea," borne on its label, were false and misleading since the statements represented and suggested that the article would be efficacious in the cure, mitigation, treatment, or prevention of cystitis and gonorrhea, whereas it would not be efficacious for such purposes. It was alleged to be misbranded further in that the statement "Sulfanilamide," borne on its label, was misleading since the statement suggested and created in the mind of the reader the impression and belief that the article, when used according to directions, "One or two tablets three times a day," would furnish the consumer with a therapeutically significant amount of sulfanilamide, whereas the article, when used according to directions, would not furnish the consumer with a significant amount of sulfanilamide, since the maximum daily dosage of the article, 6 tablets, as provided by the directions, would furnish an inconsequential amount of sulfanilamide.

On April 6, 1943, the defendants having entered pleas of guilty, the court imposed a fine of $25 on each defendant.

1015. Adulteration and misbranding of cod liver oil. U. S. v. The Swiftide Co. Plea of nolo contendere. Fine, $100. (F. D. C. No. 8783. Sample Nos. 71520-E, 80695-E.)

On January 18, 1943, the United States attorney for the District of Maine filed an information against the Swiftide Co., Portland, Maine, alleging shipment on or about February 7 and April 4, 1942, from the State of Maine into the States of Missouri and Ohio of a number of drums of cod liver oil. The article was labeled in part: "Swiftide Brand Cod Liver Oil."

It was alleged to be adulterated in that it was represented as a drug the name of which, cod liver oil, is recognized in the United States Pharmacopoeia, an official compendium, but its quality fell below the standard set forth therein since that compendium provides that cod liver oil does not have a rancid odor, that not more 1 cc. of tenth-normal sodium hydroxide is required to neutralize the acids contained in 2 grams thereof, and that, when tested for non-destearinated cold liver oil, the oil remains fluid and does not deposit stearin, whereas the article had a rancid odor, required tenth-normal sodium hydroxide in amounts varying from 1.8 to 5.18 cc. to neutralize the free acids contained in 2 grams of the article, and the Missouri lot, when tested for non-destearinated cod liver oil,

produced a solid mass, indicating that such lot was non-destearinated, and the standard of quality and purity was not declared on its label.

The Missouri lot was alleged to be misbranded in that the statement in its labeling, "Guaranteed to Contain Not Less Than 200 A. O. A. C. Units Vitamin D Not Less Than 1000 Units Vitamin A per Gramme of Oil," was false and misleading since it contained not more than 100 A. O. A. C. units of vitamin D and not more than 700 U. S. P. units of vitamin A per gram.

The Ohio lot was alleged to be misbranded in that the statement in its labeling, "Guaranteed to Contain Not Less Than 200 A. O. A. C. Units Vitamin D * * * per Gramme of Oil," was false and misleading since it contained not more than 85 A. O. A. C. units of vitamin D per gram.

On September 29, 1943, the defendant having entered a plea of nolo contendere, the court imposed a fine of $100.

1016. Adulteration and misbranding of surgical catgut. U. S. v. Flanders-Day Co. Plea of guilty. Fine, $100. (F. D. C. No. 8821. Sample Nos. 22551–F, 32801–F, 32806–F.)

On May 10, 1943, the United States attorney for the District of Massachusetts filed an information against the Flanders-Day Co., a corporation, Boston, Mass., alleging shipment on or about August 25, September 17, and October 14, 1942, from the State of Massachusetts into the States of New York and Pennsylvania of quantities of surgical catgut which was adulterated and misbranded. The article was labeled in part: (Carton) "Flanders Standard Sutures and Ligatures * * * U. S. P. Surgical Catgut Sterile," and (tubes in 2 of the shipments) "U. S. P. Surgical Catgut."

Examination of samples of the article showed that it was contaminated with viable aerobic and, in 2 of the shipments, anaerobic, spore-bearing bacteria.

The article was alleged to be adulterated in that it purported to be and was represented as a drug, surgical catgut, the name of which is recognized in the United States Pharmacopoeia (second supplement, eleventh revision), an official compendium, but its quality and purity fell below the standard set forth therein since it was not sterile and did not meet the test for sterility of solids described in that compendium.

It was alleged to be misbranded in the statements in the labeling, (cartons) "U. S. P. Surgical Catgut Sterile," and (tubes) "U. S. P. Surgical Catgut," were false and misleading.

On May 25, 1943, the defendant having entered a plea of guilty, the court imposed a fine of $100.

1017. Adulteration and misbranding of Codecol and ephedrine sulfate solution. U. S. v. Harvey Laboratories, Inc. Plea of nolo contendere. Total fine, $200. (F. D. C. No. 8834. Sample Nos. 23000–F, 23326–F.)

On April 30, 1943, the United States attorney for the Eastern District of Pennsylvania filed an information against the Harvey Laboratories, Inc., Philadelphia, Pa., alleging shipment on or about September 22 and December 12, 1942, from the State of Pennsylvania into the State of New Jersey of quantities of Codecol and ephedrine sulfate solution that were adulterated and misbranded.

Adulteration of the articles was alleged in that their strength differed in the following respects from that which they were represented to possess: The Codecol was represented to contain, in each fluid ounce, 8 grains of ammonium chloride and ½ grain of antimony potassium tartrate, whereas it contained not more than 6.73 grains of ammonium chloride and not more than 0.1 grain of antimony potassium tartrate per fluid ounce; the ephedrine sulfate solution was represented to contain 1 percent of ephedrine sulfate, whereas it contained not more than 0.78 percent of ephedrine sulfate.

The articles were alleged to be misbranded in that the statements appearing in the labeling of the Codecol, "Ammonium Chloride . . . 8 gr. Antimony Potassium Tartrate . . . ½ gr. * * * qs. . . . 1 oz.," and, "Ephedrine Sulfate 1%" borne on the bottle label of the ephedrine sulfate solution, were false and misleading.

On June 2, 1943, the defendant having entered a plea of nolo contendere, the court imposed a fine of $50 upon each of the 4 counts, a total of $200.

1018. Adulteration and misbranding of elixir of iron, quinine and strychnine phosphates. U. S. v. The Liebenthal Brothers Co. (Marlo Products Co.). Plea of guilty. Fine, $500 and costs. (F. D. C. No. 8772. Sample No. 5926–F.)

On January 29, 1943, the United States attorney for the Northern District of Ohio filed an information against the Liebenthal Brothers Co., a corporation doing business under the name of the Mario Products Co., Cleveland, Ohio, alleging

shipment on or about May 7, 1942, from the State of Ohio into the State of Missouri of a quantity of elixir of iron, quinine, and strychnine phosphates which was adulterated and misbranded.

The article was alleged to be adulterated in that it purported to be a drug the name of which is recognized in the National Formulary, an official compendium, but its strength differed from the standard set forth therein since it contained not more than 4.22 grams of quinine phosphate per 1,000 cc., whereas it should have contained 5 grams of quinine phosphate per 1,000 cc.; and the respect in which it differed from the standard set forth in the Formulary was not plainly stated on the label.

It was alleged to be misbranded in that the statements in its labeling, "Elixir Iron Quinine and Strychnine Phosphates. * * * This is not the N. F. Formula. It varies from the N. F. formula in that it contains 9.5% alcohol and 12% glycerin by volume whereas the N. F. product contains approximately 24% alcohol and 30% glycerine by volume," were false and misleading since these statements represented and suggested that the strength of the article conformed in all respects with the standard for elixir of iron, quinine and strychnine phosphates set forth in the National Formulary with the exceptions indicated, whereas its strength did not conform to the standard with the said exceptions, but differed from the standard in the further respect that it was deficient in quinine phosphate.

On April 13, 1943, the defendant having entered a plea of guilty, the court imposed a fine of $500 and costs.

1019. Adulteration and misbranding of sterile solution of chorionic gonadotropic hormone. U. S. v. Tuteur & Co., Inc. Plea of guilty. Fine, $750. (F. D. C. No. 8775. Sample No. 22909–F.)

On July 30, 1943, the United States attorney for the Southern District of New York filed an information against Tuteur & Co., Inc., New York, N. Y., alleging shipment on or about August 26, 1942, from the State of New York into the State of Pennsylvania of a quantity of the above-named product which was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess, since it purported and was represented to possess, in each 10 cc. thereof, a physiological activity equivalent to 5,000 International Units of chorionic gonadotropic hormone, and, in each cubic centimeter thereof, a physiological activity equivalent to 500 International Units of anterior pituitary-like sex hormone, whereas the article possessed, in each 10 cc., a physiological activity equivalent to not more than 1,650 International Units of chorionic gonadotropic hormone, and, in each cubic centimeter, a physiological activity equivalent to not more than 165 International Units of anterior pituitary-like sex hormone.

It was alleged to be misbranded in that the statements, "10 cc. * * * Package 5,000 International Units Sterile Solution Chorionic Gonadotropic Hormone * * * Contains Anterior pituitary-like sex hormone standardized to a potency of 500 International Units per cc.," borne on the label, were false and misleading.

On August 12, 1943, the defendant having entered a plea of guilty, the court imposed a fine of $375 on each of the 2 counts in the information, a total of $750.

1020. Adulteration and misbranding of sterile solution of chorionic gonadotropic hormone. U. S. v. 99 Vials of Sterile Solution Chorionic Gonadotropic Hormone. Decree of condemnation and destruction. (F. D. C. No. 8566. Sample No. 22909–F.)

Examination showed that the potency of this preparation was not greater than 165 International Units per cubic centimeter of chorionic gonadotropic hormone.

On October 13, 1942, the United States attorney for the Eastern District of Pennsylvania filed a libel against 99 vials of the above-named product at Philadelphia, Pa., alleging that the article had been shipped on or about August 28, 1942, from New York, N. Y., by Tuteur & Co., Inc.; and charging that it was adulterated and misbranded. Some of the vials were labeled in part: "10 cc. * * * Package 5,000 International Units * * * Contains Anterior pituitary-like sex hormone standardized to a potency of 500 International Units per cc." Other vials when shipped were labeled in part: "10 cc. * * * Package 1,000 International Units * * * Contains Anterior pituitary-like sex hormone standardized to a potency of 100 International Units per cc."; but after their receipt the shipper represented to the consignee that the labels were in error and that the product actually contained 500 International Units per cubic centimeter.

The article was alleged to be adulterated in that its strength differed from that which it purported or was represented to possess, "Anterior pituitary-like sex hormone standardized to a potency of 500 International Units per cc."

It was alleged to be misbranded in that the statements on its label, "10 cc. * * * Package 5,000 International Units * * * Chorionic Gonadotropic Hormone," and "Contains Anterior pituitary-like sex hormone standardized to a potency of 500 International Units per cc.," were false and misleading since the article had a potency materially less than 500 International Units per cubic centimeter (5,000 International Units per 10 cc.) of chorionic gonadotropic hormone.

On November 18, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1021. Adulteration of Akerite Glycerin Alternate. U. S. v. 1 Keg of Akerite (Alternate). Decree of condemnation and destruction. (F. D. C. No. 9463. Sample No. 23339–F.)

On March 1, 1943, the United States attorney for the Eastern District of Pennsylvania filed a libel against 1 keg containing approximately 48 pounds of Akerite Glycerin Alternate at Philadelphia, Pa., alleging that the article had been shipped on or about January 25, 1943, from Norwood Park, Ill., by the Akerite Chemical Works, Inc.; and charging that it was adulterated.

The product was alleged to be adulterated (1) in that its purity and quality fell below that which it purported or was represented to possess, (on the invoice) "Glycerin Alternate," since it was not an alternate for glycerin but was a poisonous mixture containing Diethylene glycol; and (2) in that a poisonous chemical compound, Diethylene glycol, had been substituted in part for the article, (in a folder entitled "Akerite Glycerin Substitute," supplied to the consignee) "Akerite Glycerin Substitute is an aqueous solution derived from dextrin, starch and corn sugar by a special process."

The article was also alleged to be adulterated under the provisions of the law applicable to foods as reported in the notices of judgment on foods, No. 5762.

On March 23, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1022. Adulteration and misbranding of Brom-Acet. U. S. v. 19 Dozen Packages of Brom-Acet. Consent decree of condemnation. Product ordered released under bond for relabeling. (F. D. C. No. 8457. Sample Nos. 13914–F, 13922–F.)

Analyses of samples of this product showed the presence of sodium bromide in amounts ranging from 10.4 to 11.9 grains per ounce.

On September 29, 1942, the United States attorney for the Southern District of California filed a libel against 19 dozen packages of Brom-Acet at Los Angeles, Calif., alleging that the article had been shipped in interstate commerce on or about June 18 and 23 and July 11, 1942, by the Purity Drug Co., Inc., from New York, N. Y.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from that which it was represented to possess. It was alleged to be misbranded in that it was fabricated from two or more ingredients and its label failed to bear a statement of the quantity or proportion of sodium bromide contained therein since the statement on the label, "Each Ounce contains Sodium Bromide 16 Grains," was not correct.

On March 2, 1943, the Purity Drug Co., Inc., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond for relabeling or reprocessing in compliance with the law. The product was satisfactorily relabeled.

1023. Adulteration and misbranding of calomel. U. S. v. 7 Cartons and 14 Cartons of Calomel. Decrees of condemnation. Product ordered released under bond for reprocessing. (F. D. C. Nos. 8901, 8951. Sample Nos. 16413–F, 16512–F, 25410–F.)

Examination showed that the chloride (mercury bichloride) content of one portion of this product (7 cartons) was from 2 to 4 times the limit permitted by the United States Pharmacopoeia, and that of the other portion was from 3.5 to 8 times such limit.

On November 20 and December 18, 1942, the United States attorneys for the Eastern District of Virginia and the District of Colorado filed libels against 7 cartons of calomel at Richmond, Va., and 14 cartons at Denver, Colo., each carton containing 100 bottles, alleging that the article, which had been consigned by the Day Chemical Co., had been shipped on or about October 10 and 12, 1942, from Newark, N. J.; and charging that it was adulterated and misbranded. The

article was labeled in part: "4 Oz. * * * Calomel (Mild Mercurous Chloride) U. S. P. XI Poison Mfd. by F. W. Berk Co., Inc., Wood Ridge, N. J. Day Chemical Co., * * * Contractor."

The article was alleged to be adulterated in that it purported to be and was represented as a drug, the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its purity fell below the standard set forth therein since the Pharmacopoeia provides that, when tested as prescribed, the ether extract from 2 grams of calomel shall show no more chloride (mercury bichloride) than corresponds to 0.1 cc. of 50th normal hydrochloric acid, whereas the article, when tested by the method prescribed in that compendium, contained more chloride than corresponded to 0.1 cc. of 50th normal hydrochloric acid.

It was alleged to be misbranded in that the statement appearing on its label, "Calomel (Mild Mercurous Chloride) U. S. P. XI," was false and misleading since the article was not calomel (mild mercurous chloride) U. S. P. XI.

On January 18 and 28, 1943, F. W. Berk & Co., Inc., New York, N. Y., having appeared as claimant for the lot at Richmond, and F. W. Berk & Co., Inc., and the Day Chemical Co. having appeared as claimants for the lot at Denver, and having admitted the allegations of the libels, judgments of condemnation were entered and the product was ordered released under bond for reprocessing under the supervision of the Food and Drug Administration.

1024. Adulteration of Special Enteric Tablets. U. S. v. 7,700 Special Enteric Tablets. Decree of condemnation and destruction. (F. D. C. No. 9599. Sample No. 3149–F.)

Analysis of a sample of this product showed that each tablet contained not more than 1.01 grains of nicotine sulfate per tablet.

On March 23, 1943, the United States attorney for the District of Nebraska filed a libel against 7,700 Special Enteric Tablets at Omaha, Nebr., alleging that the article had been shipped on or about July 30, 1942, from St. Louis, Mo., by Charles H. Dietz, Inc.; and charging that it was adulterated. The article was labeled in part: "Special Enteric SC Red Tablet Rx 2940 Each C. T. contains: Nicotine sulphate___1.9375 gr." (the letters C. T. meaning compressed tablet).

The article was alleged to be adulterated in that its strength differed from that which it was represented to possess.

On June 9, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1025. Adulteration and misbranding of lubricating jelly. U. S. v. 2,877 Jars and 3,945 Jars of Lubricating Jelly. Consent decree of forfeiture and destruction. (F. D. C. Nos. 8245, 8267. Sample Nos. 5163–F, 5440–F, 29128–F.)

On August 27, 1942, the United States attorneys for the Northern Districts of Georgia and Ohio filed libels against 2,877 jars and 3,945 jars of lubricating jelly at Atlanta, Ga., and Toledo, Ohio, respectively, alleging that the article had been shipped on or about July 15 and August 17, 1942, by the Lambert Pharmacal Co., from St. Louis, Mo.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its purity or quality fell below that which it purported or was represented to possess, "Sterile."

It was alleged to be misbranded in that the designation "Sterile" was misleading since it created the impression that the article was sterile, whereas it was not sterile but was contaminated with living anaerobic and aerobic spore-bearing bacteria.

On October 13, 1942, the Lambert Pharmacal Co. having appeared as claimant for the lot at Toledo, the action was ordered transferred to the Northern District of Georgia for consolidation with the proceeding against the Atlanta lot. After the consolidation and in accordance with a stipulation filed by the parties, an order was entered on October 19, 1942, providing for the removal of the consolidated case for trial to the Eastern District of Illinois. On November 4, 1942, an answer was filed by the claimant denying that the article was adulterated or misbranded, and on April 6, 1943, the claimant filed a petition for re-delivery of the product for the purpose of reprocessing it. On the same date the court ordered it released under bond, conditioned that it be reprocessed under the supervision of the Food and Drug Administration. On July 22, 1943, by consent of the claimant, judgment was entered vacating the order of April 6, 1943, and providing for the forfeiture and destruction of the product.

1026. Adulteration and misbranding of lubricating jelly. U. S. v. 120 Packages and 13½ Dozen Packages of Lubricating Jelly. Decrees of condemnation and destruction. (F. D. C. Nos. 9355, 9356. Sample Nos. 29054–F, 38019–F.)

On February 10 and 13, 1943, the United States attorneys for the Northern Districts of Illinois and Georgia filed libels against 120 packages of lubricating

jelly at Chicago, Ill., and 13½ dozen packages at Atlanta, Ga., alleging that the article had been shipped on or about December 9 and 31, 1942, from Detroit, Mich., by White Cross Pharmacals, Inc.; and charging that it was adulterated and misbranded. The article was labeled in part: "American Surgical Lubricating Jelly * * * Made for American Hospital Supply Corp.," or "White Cross Surgical Lubricating Jelly."

The article was alleged to be adulterated in that its purity and quality fell below that which it was represented to possess, "Sterilized."

It was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that the article was sterile and was a suitable lubricant for surgical use were false and misleading since the article was not sterile but was contaminated with living micro-organisms and was not suitable for such use.

On April 8 and 12, 1943, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

1027. Adulteration and misbranding of Pantabee. U. S. v. 12 Bottles of Pantabee. Decree of condemnation. Product ordered delivered for the use of a public institution. (F. D. C. No. 9410. Sample No. 24197–F.)

Biological assay showed that the article contained not more than 250 International Units of vitamin B_1 per capsule.

On February 20, 1943, the United States attorney for the District of Columbia filed a libel against 12 bottles, each containing 50 capsules, of Pantabee at Washington, D. C., alleging that the article had been shipped on or about January 13, 1943, from Richmond, Va., by Charles C. Haskell & Co., Inc.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it was represented on its label to possess, 333 International Units of vitamin B_1.

It was alleged to be misbranded in that the statement "Each capsule contains: Vitamin B_1 . . . 333 International Units," which appeared on its label, was false since each capsule did not contain that amount of vitamin B_1.

It was also alleged to be adulterated and misbranded under the provisions of the law applicable to foods as reported in the notices of judgment on foods, No. 5774.

On June 30, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to a public institution.

1028. Adulteration and misbranding of elixir thiamine hydrochloride. U. S. v. 52 Bottles of Elixir Thiamine Hydrochloride. Decree of condemnation. Product ordered delivered to charitable institutions. (F. D. C. No. 9591. Sample No. 23501–F.)

Examination showed that this product contained substantially less than 250 International Units (USP Unit) of vitamin B_1 per fluid ounce.

On March 19, 1943, the United States attorney for the Eastern District of Pennsylvania filed a libel against 52 bottles, each containing 1 gallon, of the above-named product at Philadelphia, Pa., alleging that the article had been shipped on or about February 2, 1943, from Newark, N. J., by the Standard Drug Co.; and charging that it was adulterated and misbranded. A portion of the article (35 bottles) was labeled in part: "Standard Elixir Vitamin B_1 N. J. F. Elixir Thiamin Hydrochloride. Each fluid ounce contains 500 Intern. Units Vitamin B_1." The remainder of the article (17 bottles) had been relabeled by the consignee and at the commencement of the libel proceedings was labeled in part: "Elixir Thiamine Hydrochloride * * * Each fluid ounce contains: Thiamine Hydrochloride—1.5 mg. (equivalent to Vitamin B–1—500 Units)."

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it was represented to possess.

It was alleged to be misbranded in that the following statements on the bottles bearing the original labels: "Each fluid ounce contains 500 Intern. Units Vitamin B_1"; and the following statements on the labels of the relabeled portion: "Each Fluid ounce Contains: Thiamine Hydrochloride—1.5 mg. (equivalent to Vitamin B–1—500 Units)" were false since the article contained a lesser amount of vitamin B_1 per fluid ounce.

The article was also alleged to be adulterated and misbranded under the provisions of the law applicable to foods as reported in notice of judgment on food No. 5779.

On May 10, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered to be delivered to charitable institutions.

1029. Adulteration and misbranding of vitamin B elixir. U. S. v. 33 Bottles of Hart's Vitamin B Elixir. Default decree of condemnation and destruction. (F. D. C. No. 8173. Sample No. 70908–E.)

This product contained 13.8 milligrams of nicotinic acid per fluid ounce.

On August 24, 1942, the United States attorney for the Northern District of Georgia filed a libel against 33 bottles, each containing ½ pint, of Hart's Vitamin B Elixir at Atlanta, Ga., alleging that the article had been shipped on or about June 8, 1942, from New Orleans, La., by E. J. Hart and Co., Ltd.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it was represented to possess on its label, 20 milligrams of nicotinic acid per fluid ounce.

It was alleged to be misbranded in that the label statement, "Each Fluidounce contains: * * * Nicotinic Acid 20 mg.," was false.

It was also alleged to be adulterated and misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods, No. 5775.

On May 6, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1030. Adulteration and misbranding of prophylactics. U. S. v. 8 Gross Packages of Kaps. Default decree of condemnation. Product ordered disposed of as waste rubber for war purposes. (F. D. C. No. 8106. Sample No. 16844–F.)

Samples of this product were found to be defective because of the presence of holes.

On August 12, 1942, the United States attorney for the Eastern District of New York filed a libel against 8 gross packages of Kaps at Brooklyn, N. Y., alleging that the article had been shipped in interstate commerce on or about July 22, 1942, by Rubber Research Products Corporation from Jersey City, N. J.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its quality fell below that which it purported or was represented to possess since an article containing holes is not suitable for use as a prophylactic.

It was alleged to be misbranded in that the following statements appearing on the labeling were false and misleading since they represented and suggested that the article was free from defects, whereas it was not: (One dozen carton and three-unit carton) "Each one of the Kaps has been filled to at least ten times it normal capacity with water under pressure; then squeezed and kneaded in an effort to make a hole appear—even where only a weak spot may have existed before. Insist on water-tested merchandise." (Instruction sheet) "Notice: The enclosed sheath has been 'water tested' by expanding, under water pressure, to at least ten times its normal capacity—then examined closely for any detectable leak."

On May 5, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to the Food and Drug Administration for the purpose of damaging and disposing of it as waste rubber for war purposes.

1031. Adulteration and misbranding of Red Cross prophylactics and Blue Cross chemical prophylactic units. U. S. v. 959 Packages of Red Cross Prophylactics and 3,744 Packages of Blue Cross Chemical Prophylactic Units. Default decrees ordering destruction of the products. (F. D. C. Nos. 8950, 9119. Sample Nos. 12174–F, 15716–F.)

These two products contained, among other things, a tube labeled "0.25% Silver Picrate Jelly." Analyses of the jelly showed that it contained, in the case of the Red Cross prophylactics, 0.085 percent of silver picrate, and in the case of the Blue Cross chemical units 0.052 percent of silver picrate.

On December 8, 1942, and January 2, 1943, the United States attorneys for the Western District of Washington and the District of Utah filed libels against 959 packages of Red Cross prophylactics at Seattle, Wash., and 3,744 packages of Blue Cross chemical prophylactic units at Salt Lake City, Utah, alleging that the articles had been shipped on or about October 19 and November 6, 1942, from San Diego and Los Angeles, Calif., by the Schabelitz Research Laboratories; and charging that they were adulterated and misbranded. The Red Cross prophylactics were labeled in part with a design of a red cross and the figure "101," and the prophylactic unit was labeled in part: "Chemical Prophylactic Unit For Armed Forces Only 80," together with a design of a blue cross.

The articles were alleged to be adulterated in that their strength differed from that which they purported or were represented to possess, "0.25% Silver Picrate Jelly."

They were alleged to be misbranded in that the statement on their labels "0.25% Silver Picrate Jelly" was false and misleading.

On September 16, 1943, no claimant having appeared, judgment of condemnation and destruction was entered against the product at Seattle. On January 29, 1944, the Schabelitz Research Laboratories, claimant for the lot at Salt Lake City, having failed to file an answer, default was entered against the claimant and its claim was dismissed. On April 29, 1944, judgment was entered against the lot, ordering that it be destroyed.

1032. Adulteration and misbranding of first-aid dressings and bandages, compresses, and adulteration of gauze bandages. U. S. v. 60 Cases and 38,100 Cartons of First Aid Dressings, 40,000 and 8,000 Packages of Bandage Compresses, and 651 Dozen Packages of Gauze Bandages. Decrees of condemnation. A portion of the bandage compresses and all of the other products ordered released under bond for reprocessing; remainder of the bandage compresses ordered delivered to the Food and Drug Administration. (F. D. C. Nos. 8582, 8952, 9013, 9029, 9256. Sample Nos. 5583–F, 10082–F, 25560–F, 31307–F, 31359–F, 31606–F, 31619–F.)

Examination showed that these products were not sterile but were contaminated with living micro-organisms.

Between October 19, 1942, and January 26, 1943, the United States attorneys for the Southern District of Ohio, the Eastern District of Virginia, and the Western District of Texas filed libels against 60 cases, each containing 300 first-aid dressings, and 38,100 cartons of first-aid dressings and 40,000 packages of bandage compresses at Columbus, Ohio, 8,000 packages of bandage compresses at San Antonio, Tex., and 651 dozen packages of gauze bandages at Richmond, Va., alleging that the articles, which had been consigned by the Acme Cotton Products Co., Inc., had been shipped within the period from on or about September 19 to December 7, 1942, from Dayville, Conn., and Worcester, Mass.; and charging that the gauze bandages were adulterated and that the other articles were adulterated and misbranded. The first aid dressings at Columbus were labeled in part: "Large First Aid Dressing United States Army Carlisle Model Sterilized," and (portion) "Sterilized Red Color indicates back of dressing. Put other side next to wound." The gauze compresses at Columbus were labeled in part: "Four Dressings Sterilized 2 Inch Bandage Compress." The articles at San Antonio and Richmond were labeled in part: "3 inch * * * Gauze Bandage," or "1 Dressing Sterilized 4 inch Bandage Compress."

The gauze bandages were alleged to be adulterated in that they purported to be and were represented as a drug, the name of which is recognized in the United States Pharmacopoeia, an official compendium, but their quality and purity fell below the standard set forth therein since the Pharmacopoeia provides that gauze bandage must be sterile and shall meet the requirements of the sterility test for solids described in the Pharmacopoeia, and their difference in quality and purity from that standard was not stated on their label.

The first-aid dressings and the bandage compresses were alleged to be adulterated in that their purity and quality fell below that which they purported or were represented to possess, "Sterilized." They were alleged to be misbranded in that the statements appearing in their labeling which represented and suggested that the articles were sterile were false and misleading.

On January 16 and February 4, 1943, the Acme Cotton Products Co., Inc. claimant, having admitted the allegations of the libels against the products at Columbus and Richmond, judgments of condemnation were entered and the products were ordered released under bond for reprocessing under the supervision of the Food and Drug Administration. On March 18, 1943, no claimant having appeared for the bandage compresses at San Antonio, judgment of condemnation was entered and the product was ordered to be delivered to the Food and Drug Administration.

1033. Adulteration and misbranding of gauze bandages and first aid, treated strips, and misbranding of Tip Top gauze and Chatham bandage. U. S. v. 6⅔ Gross Packages and 162 Dozen Boxes of Gauze Bandages, 48 Cartons of First-Aid Treated Strips, 1,983 Dozen Packages of Tip Top Gauze, and 176 Dozen Packages of Chatham Bandage. Decrees of condemnation. Tip Top Gauze, Chatham Bandage, and a portion of the gauze bandages ordered released under bond for sterilization; first aid, treated strips and remainder of gauze bandages ordered destroyed. (F. D. C. Nos. 8008, 9065, 9074, 9816. Sample Nos. 553–F, 5845–F, 5846–F, 21666–F, 21701–F.)

On July 28 and December 24, 1942, and January 5 and April 19, 1943, the United States attorneys for the Northern District of Illinois, and the Western Districts of Tennessee and Pennsylvania filed libels against 48 cartons, each containing 36 envelopes, of first aid, treated strips at Chicago, Ill., 1,983 dozen packages of Tip Top gauze and 176 dozen packages of Chatham bandage at

Memphis, Tenn., and 6⅔ gross packages and 162 dozen boxes of gauze bandages at Pittsburgh, Pa., alleging that the artciles had been shipped within the period from on or about June 26, 1942, to March 10, 1943, by the Gotham Sales Co., Inc., from New York, N. Y.; and charging that they were misbranded and that the first aid, treated strips and the gauze bandages were also adulterated. The articles were labeled in part: "Sani+Cross Waterproof First Aid Treated Strips * * * Distributed by Gero Products, Boston, Mass.," "Tip Top Gauze Bandage," "Chatham Bandage [or "Gauze Bandage"] * * * Distributors Chatham Sundries Co. New York, N. Y.," or "R112 Gauze Bandage."

The first aid, treated strips were alleged to be adulterated in that they purported to be and were represented as an article, adhesive absorbent gauze, described in the United States Pharmacopoeia, an official compendium, but the article differed from the standard set forth in that compendium since it failed to meet the requirements of the sterility test for solids.

They were alleged to be misbranded in that the statements appearing on their label, "Sani+Cross First Aid Treated Strips Wash Wound with an Antiseptic—Remove Crinoline and Apply Gauze Pad to the Wound," were false and misleading since these statements represented and suggested that the strips were a safe, sanitary, and appropriate bandage for first aid use on minor cuts, wounds, and abrasions, whereas they were not a safe, sanitary, and appropriate bandage for such use because they were contaminated with living bacteria. They were alleged to be misbranded further in that they were in package form and their label failed to bear a statement of the quantity of the contents.

A portion of the gauze bandages (6⅔ gross packages) was alleged to be adulterated in that it purported to be and was represented as a drug, the name of which is recognized in an official compendium, but its quality and purity fell below the standard set forth therein since it was not sterile but was contaminated with viable micro-organisms. The remainder of the gauze bandages was alleged to be adulterated in that its purity and quality fell below that which it purported and was represented to possess, "Sterilized."

The gauze bandages, Tip Top gauze, and Chatham bandage, were alleged to be misbranded in that the statements appearing in their labeling, "Sterilized After Packaging," and the additional statement in the labeling of the 162 boxes of gauze bandages, "Designed to Perfectly Meet First Aid Requirements," were misleading since they created the impression that the articles were sterile, whereas they were not sterile but were contaminated with viable micro-organisms.

On September 24, 1942, and March 13, 1943, the Gotham Sales Co., Inc., claimant, having admitted the allegations of the libels against the Tip Top gauze, Chatham bandage, and a portion of the gauze bandages (162 dozen boxes), judgments of condemnation were entered and the products were ordered released under bond for sterilization. On March 1 and June 8, 1943, no claimant having appeared for the other products seized, judgments of condemnation were entered and it was ordered that they be destroyed.

1034. Adulteration and misbranding of adhesive absorbent gauze. U. S. v. 75 ½-Gross Packages of Sani+Cross Adhesive Strips, 264 Gross of Tip Top Adhesive Strips, and 4 ½-Gross Packages of Sani+Cross Waterproof First Aid Treated Strips. Default decrees of condemnation and destruction. (F. D. C. Nos. 9209, 9326, 9964. Sample Nos. 18482–F, 23285–F, 44467–F.)

Examination showed that these products consisted of a small pad of gauze affixed to a strip of adhesive plaster.

Between January 19 and May 19, 1943, the United States attorneys for the Southern District of New York and the Middle District of Pennsylvania filed libels against 75 ½-gross packages of Sani-Cross adhesive strips and 264 gross of Tip Top adhesive strips at New York, N. Y., and against 4 ½-gross packages of Sani-Cross waterproof first aid, treated strips at Harrisburg, Pa., alleging that the articles, which had been consigned by the Gero Products, Inc., had been shipped on or about December 23, 1942, and January 12 and March 30, 1943, from Boston and South Boston, Mass.; and charging that they were adulterated and misbranded. The Tip Top adhesive strips were labeled in part: "Distributed by Gotham Sales, N. Y., N. Y."

The articles were alleged to be adulterated in that they purported to be a drug, adhesive absorbent gauze (adhesive absorbent compress), the name of which is recognized in the United States Pharmacopoeia, an official compendium, but their quality and purity fell below the standard set forth in that compendium since they were not sterile but were contaminated with living micro-organisms, and

their difference in quality and purity from the standard set forth in the compendium was not plainly stated on the labels.

The first aid, treated strips, were alleged to be misbranded in that they were in package form and the label failed to bear a statement of the quantity of the contents; and in that the statements appearing upon the label, "Sani+Cross First Aid Treated Strips For minor cuts, wounds, abrasions Directions Wash wound with an antiseptic. Remove crinoline and apply gauze pad to the wound," were false and misleading since those statements represented and suggested that the article was a safe and appropriate bandage for first aid use on minor cuts, wounds, and abrasions, whereas it was not a safe and appropriate bandage for such use but was contaminated with living micro-organisms.

The other articles were alleged to be misbranded in that the statements, "Sani+Cross Adhesive Strips For Home, Factory, and Sports use. Directions Wash wound with an antiseptic. Remove crinoline and apply gauze pad to the wound," appearing in the labeling of the Sani-Cross adhesive strips, and similar statements in the labeling of the Tip Top adhesive strips, were false and misleading since they created the impression that the articles were safe and appropriate bandages for first aid use on broken skin, whereas they were not safe and appropriate bandages for such uses, but were contaminated with living micro-organisms.

The first aid, treated strips and the Sani-Cross adhesive strips were alleged to be misbranded further in that the designation "Sani+Cross," appearing in the labeling, was false and misleading since it created the impression that the articles were sterile and sanitary dressings, whereas they were not sterile and sanitary.

On February 9, March 10, and June 26, 1943, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

1035. Adulteration and misbranding of gauze bandage. U. S. v. 102 Dozen Packages of Gauze Bandage. Default decree of condemnation and destruction. (F. D. C. No. 8646. Sample No. 12139–F.)

On October 28, 1942, the United States attorney for the Western District of Washington filed a libel against 102 packages of gauze bandage at Seattle, Wash., alleging that the article had been shipped in interstate commerce on or about July 25, 1942, from New York, N. Y., by C. I. Lee and Co.; and charging that it was adulterated and misbranded. The article was labeled in part: "Gauze Bandage 2 Inch * * * Distributors Chatham Sundries Co. New York, N. Y."

The article was alleged to be adulterated in that its purity and quality fell below that which it purported and was represented to possess, "Sterilized."

It was alleged to be misbranded in that the statement appearing in its labeling "Sterilized after packaging," was misleading since it created the impression that the article was sterile, whereas it was not sterile but was contaminated with living gram-positive spore-bearing bacilli.

On September 16, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1036. Adulteration and misbranding of bandage gauze. U. S. v. 4,379 Dozen Packages of Bandage Gauze. Consent decree of condemnation. Product released under bond to be brought into compliance with the law. (F. D. C. No. 9251. Sample No. 32370–F.)

On January 27, 1943, the United States attorney for the Northern District of Ohio filed a libel against 4,379 dozen packages of bandage gauze at Toledo, Ohio, alleging that the article had been shipped in interstate commerce on or about December 3, 1942, by Convenience, Inc., from Greenville, S. C.; and charging that it was adulterated and misbranded. The article was labeled in part: "Bandage: Gauze, Roller, Plain Sterilized."

The article was alleged to be adulterated in that it purported to be and was represented as a drug, the name of which is recognized in an official compendium, the United States Pharmacopoeia (twelfth revision), but its quality and purity fell below the standard set forth therein since it was not sterile but was contaminated with viable micro-organisms.

It was alleged to be misbranded in that the designation "Sterilized," appearing in the labeling, was false and misleading.

On March 18, 1943, Convenience, Inc., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond to be brought into compliance with the law under the supervision of the Food and Drug Administration.

1037. Adulteration and misbranding of gauze bandages. U. S. v. 10,000 Dozen Packages of Gauze Bandages (and 8 other seizure actions against gauze bandages). Consent decrees of condemnation. Product ordered released under bond for reprocessing. (F. D. C. Nos. 9309, 9371, 9411, 9456, 9529, 9530, 9818, 9819, 10207, 12296. Sample Nos. 6769–F, 37407–F, 37578–F, 37579–F, 42403–F, 42404–F, 45722–F, 45727–F, 45766–F, 45785–F to 45787–F, incl., 45822–F, 67812–F.)

Examination showed that this product was not sterile but was contaminated with living micro-organisms.

Between February 4, 1943, and May 3, 1944, the United States attorneys for the Eastern District of Virginia, the Western District of Washington, the Eastern District of Missouri, and the Western District of Kentucky filed libels against the following quantities of gauze bandages from 1 to 4 inches in width: 10,000 dozen packages, 6,900 packages, each containing 1 dozen, 120 cartons, each containing 100 dozen, 217 cases, each containing 100 dozen, and 345 cases, each containing 50 dozen, at Richmond, Va.; 621 dozen packages and 318 packages at Seattle, Wash.; 531 dozen packages at St. Louis, Mo.; and 25 cases, each containing 50 dozen, at Louisville, Ky. It was alleged that all lots had been shipped within the period from on or about October 8, 1942, to March 23, 1944, by the Marsales Company, Inc., from New York, N. Y., and East Lyme, Niantic, Conn., with the exception of a portion of the Richmond lot, which was alleged to have been shipped from San Antonio, Tex., by the San Antonio Quartermaster Depot, and a portion of the Seattle lot, which was alleged to have been shipped by the Indian Service Warehouse from St. Louis, Mo.; and it was charged that the bandages were adulterated and misbranded. Portions of the article were labeled in part: "Bandage [or "Bandages"] Gauze Roller Plain Sterilized," or "Marco Sterilized When Packed Gauze Bandage."

The lot at Louisville was alleged to be adulterated in that its purity and quality fell below that which it purported and was represented to possess, "sterilized." The remaining lots were alleged to be adulterated in that they purported to be and were represented as a drug, the name of which is recognized in an official compendium, the United States Pharmacopoeia (twelfth revision), but their quality and purity fell below the standard set forth in that comperdium since they were not sterile.

All lots were alleged to be misbranded in that the statements appearing in their labeling which represented that they were sterile were false and misleading.

Between March 1, 1943, and June 19, 1944, the Marsales Company, Inc., claimant, having consented to the entry of the decrees, judgments of condemnation were entered and the product was ordered released under bond for reprocessing under the supervision of the Food and Drug Administration.

1038. Adulteration and misbranding of absorbent cotton. U. S. v. 464 Packages of Absorbent Cotton. Consent decree of condemnation. Product ordered released under bond for processing. (F. D. C. No. 9156. Sample No. 6581–F.)

On January 9, 1943, the United States attorney for the Eastern District of Arkansas filed a libel against 464 1-ounce packages of absorbent cotton at Little Rock, Ark., alleging that the article had been shipped in interstate commerce on or about September 16 and November 13, 1942, from Cape Girardeau, Mo., by the American White Cross Laboratories; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth therein since the article did not conform to the requirements of the test for sterility of solids prescribed in that compendium, but was contaminated with gram-positive bacilli.

It was alleged to be misbranded in that the statements appearing upon its label, "U. S. P. Absorbent Cotton * * * Sterilized After Packaging Best Hospital Quality U. S. P. Absorbent Cotton means that this cotton conforms to all requirements of the United States Pharmacopoeia. This cotton is sterilized twice—once during the process of manufacture and then again after packaging. U. S. P. Absorbent Cotton meets government specifications in every respect," were false and misleading since the article was not sterile and did not comply with the specifications of the United States Pharmacopoeia.

On June 29, 1943, the American White Cross Laboratories, Inc., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond, conditioned that it

be processed so as to comply with the law, under the supervision of the Food and Drug Administration.

1039. Adulteration and misbranding of silk sutures. U. S. v. 7,200 Packages and 7,200 Packages of Silk Sutures. Decrees of condemnation. Portion of product ordered released under bond for reprocessing and relabeling, and remainder ordered destroyed. (F. D. C. Nos. 9255, 9396. Sample Nos. 6509–F, 32823–F.)

Each package of these sutures contained 3 smaller packages labeled in part: "Size 00," "Size 1," or "Size 2." The "Size 2" sutures were contaminated with living micro-organisms.

On January 27 and February 19, 1943, the United States attorneys for the Eastern District of Missouri and the Northern District of New York filed libels against 7,200 packages of silk sutures at St. Louis, Mo., and 7,200 packages at Binghamton, N. Y., alleging that the article had been shipped in interstate commerce on or about December 17 and 28, 1942, by the Gudebrod Brothers Silk Co., Inc., from Pottstown, Pa.; and charging that it was adulterated and misbranded. The article was labeled in part: "Sizes 00–1–2 Two 18" Strands of Each Sterile * * * Braided Silk Sutures."

The "Size 2" sutures were alleged to be adulterated in that they purported to be and were represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but their quality and purity fell below the standard set forth therein since the sutures did not meet the test for sterility of solids as required by that compendium.

They were alleged to be misbranded in that the statement on the label, "Sterile," was false and misleading.

On April 13, 1943, the Gudebrod Brothers Co., Inc., having appeared as claimant for the lot at St. Louis, and having consented to the entry of a decree, judgment of condemnation was entered and that lot was ordered released under bond for reprocessing and relabeling under the supervision of the Food and Drug Administration. On May 4, 1943, no claimant having appeared for the lot at Binghamton, judgment of condemnation was entered and the lot was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

DRUGS FOR HUMAN USE

1040. Misbranding of Colusa Natural Oil, Colusa Natural Oil Capsules, and Colusa Natural Oil Hemorrhoid Ointment. U. S. v. Empire Oil & Gas Corporation and Chester Walker Colgrove (Colusa Products Co.) Pleas of not guilty. Tried to a jury. Verdict of guilty. Fine of $500 and 6 months in jail imposed against individual defendant on each of the 3 counts, the jail sentences to run concurrently and terminate upon payment of fine. Corporate defendant fined $3. Fines deposited in escrow and appeal noted. Judgment reversed by appellate court and case remanded for retrial. Pleas of nolo contendere thereafter entered. Defendants given same sentences as those originally imposed. (F. D. C. No. 6408. Sample Nos. 65381–E to 65383–E, incl.)

On March 24, 1942, the United States attorney for the Northern District of California filed an information against the Empire Oil & Gas Corporation, trading as the Colusa Products Co. at Berkeley, Calif., and against Chester Walker Colgrove, president and treasurer of the corporation, alleging shipment on or about January 31, 1941, from the State of California into the State of New Mexico of quantities of the above-named products which were misbranded.

Analyses of the Colusa Natural Oil and the Colusa Natural Oil Capsules showed that they consisted of crude petroleum oil containing 0.75 percent of sulfur, and that they did not contain camphor, turpentine, and iodine or iodine compounds, or possess any radio activity.

These articles were alleged to be misbranded in that the statements in their labeling which represented and suggested that, when used alone or in conjunction with each other, they would be efficacious in the treatment of eczema, psoriasis, acne, ringworm, athlete's foot, burns, cuts, poison ivy, and varicose ulcers; that they would act on surface skin irritations as a stimulant and would increase circulation and aid in healing; that they would be efficacious to relieve discomfort and pain; that they would be efficacious to inhibit the spreading of skin irritations and to restore the normal skin surface; and that they would be efficacious to kill or check disease germs were false and misleading since the articles were not efficacious for such purposes.

*See also Nos. 1001–1020, 1023, 1025–1039.

Analysis of the Colusa Natural Oil Hemorrhoid Ointment showed that it consisted essentially of zinc oxide, crude petroleum oil, and small proportions of camphor, menthol, and benzocaine incorporated in a base of lanolin and beeswax.

The article was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that it would be efficacious in the treatment of hemorrhoids and piles were false and misleading since it would not be efficacious for such purposes. It was alleged to be misbranded further in that it was in package form and its label did not bear an accurate statement of the quantity of the contents in terms of weight or measure since it didn't bear a statement of the quantity of the contents.

On June 23, 1942, the defendants having entered pleas of not guilty, the case came on for trial before a jury. On June 30, 1942, the trial was concluded and the jury returned a verdict of guilty as to each defendant. On July 8, 1942, the court imposed against the corporate defendant a fine of $1 upon each of 3 counts, a total of $3; and against the individual defendant a fine of $500 upon each of 3 counts, a total of $1,500, together with a sentence of 6 months in jail on each count, the jail sentences to run concurrently and terminate upon payment of his fine. The fines were deposited in escrow and an appeal was noted.

On June 28, 1943, the circuit court of appeals for the Ninth Circuit reversed the judgment of the district court, handling down the following opinion:

STEPHENS, *Circuit Judge:*

"Empire Oil and Gas Corporation, (a corporation) and Chester Walker Colgrove, trading as Colusa Products Company, were informed against in three separate counts charging the violation of the Act of Congress (June 25, 1938), known as the Federal Food, Drug, and Cosmetic Act [52 Statutes at Large, 1040, 21 USCA, §§ 331 (a), 352 (a)]. The corporation and Colgrove were tried by judge and jury and were convicted upon all three counts. Judgments and sentence followed and both the corporation and Colgrove appeal therefrom.

"It is charged in all three counts that packages containing drugs which were sent into interstate commerce were misbranded in that the branding falsely claimed the drugs were efficacious in the treatment of various named diseases.

"In counts I and II the following skin diseases are specifically named: eczema, psoriasis, acne, ringworm, Athlete's Foot, burns, cuts, poison ivy and varicose ulcers. In count III the disease named is hemorrhoids or piles.

"As to count III, an additional charge of misbranding is made that the labels on jars of ointment did not bear an accurate statement of the quantity of the contents in terms of weight and measure.

"The evidence establishes without conflict that the Empire Oil and Gas Corporation, with Chester Walker Colgrove as its president and active manager in immediate charge of the business, was conducting the business of producing and marketing products, the base of which came from a California oil well. As alleged in the information, appellants placed some of such products in the course of interstate commerce. The oil produced from the well is called Colusa Oil and is claimed by the producers and marketers to have remarkable remedial qualities. It is offered for sale as a liquid and as an ointment. The immediate containers of the products are labeled and packed in cartons or boxes which contain advertising matter related to the efficacy of the product as a remedy for a number of skin diseases and for hemorrhoids.

"In their opening brief on appeal, appellants treat their assignments of error under six major points, and we shall treat them in their order of presentation therein.

"It is claimed that the evidence is insufficient. There is no question but that there is great conflict upon the issue of misbranding as to the efficacy of the remedies. As will hereinafter appear, there was error committed which greatly affected the evidence upon this issue. As to count III, there is substantial evidence that the remedy containers went into interstate commerce without the required quantity of contents being printed upon the label [21 USCA, §§ 331 (a), 352 (a), 352 (b) (2)]. No error can be predicated upon this point.

"Appellants claim highly prejudicial error by reason of the trial court's rulings as to the testimony of Dr. C. E. Von Hoover.

"Dr. Von Hoover was presented as an expert witness for the defense, and his qualifying testimony revealed the following: Between 1922 and 1924 he attended New York Chemical College, now City College. There he spent eighteen months in the study of biochemistry and was awarded the Smedley D. Butler scholarship. (For convenience we quote definitions from Webster's New International Dictionary, Second Edition, of certain technical terms.)

Biochemistry: 'The chemistry plant and animal life; biological, or physiological chemistry.'

From 1924 to 1926 he attended Kings College in London, receiving therefrom the degree of Master of Science. While there he studied pharmacology and general science, including microbiology.

Pharmacology: '1. The science of drugs, including materia medica and therapeutics: 2. The materials of this science: the properties and phenomena of drugs especially with relation to their therapeutic value.'

Materia medica: 'a. Material or substance of remedies. b. That branch of medical science which treats of the nature and properties of all the substances employed for the cure of diseases.'

Therapeutics: 'That part of medical science which treats of the application of remedies for diseases; therapy.'

Therapy: 'Treatment of disease.'

Microbiology: 'The science or study of microbes.'

He attended the University of Vienna two years under the Smedley D. Butler scholarship, receiving the degree of Doctor of Science. There he studied microbiology, laboratory pharmacology and general science and materia medica, with the use of the American pharmacopoeia. These subjects are the same as lead to a degree of M. D. The degree of M. D. also requires practice on patients. He is a professional dermatologist.

Dermatology: 'The science which treats of the skin, its structure, functions and diseases.'

He was with Goodman Research Laboratory, New York, for a year on the clinical staff, testing pharmaceuticals and ointments and practicing general pharmaceutical chemistry. In collaboration with Medical Doctors and Doctors of Science he there tested the therapeutic value of and dangers of medicinal preparations to human patients. In 1930 he established a clinical testing agency under his name at San Antonio, Texas, receiving business in that line of endeavor from high grade manufacturing chemists and especially from well-known firms manufacturing skin disease preparations. He has been so employed by Vitamin Research Company who manufacture synthetic vitamins. In his clinic a Medical Doctor diagnoses and prescribes. An assistant in the clinic is Dr. Beal, for some time United States Public Health Officer and surgeon. Another Medical Doctor assistant is a former Health Officer of San Antonio and past Trustee of the American Medical Society. Another assistant is Major Burby, retired Trustee of the American Veterinary Association, who acts as veterinary consulter in the handling of small animal practice and experimentation.

"While Dr. Von Hoover was on the witness stand as a witness for the defendants, he was shown a report designated as Exhibit 'L' for identification relating to the effect of Colusa Oil on dogs suffering from mange. He testified: 'It is my report. I prepared it; that is my report of the results of the application of Colusa Natural Oil to the skin of animals; associated with me was Dr. Burby, a veterinarian.—I am not a veterinary.'

"Mr. Zirpoli, the assistant district attorney: 'And this is a veterinarian's report?'

"A. 'You see my name on the other side as the laboratory man, * * * the man that made the findings in the presence of the veterinarian. He couldn't make those tests because he is not qualified in bacteriology. * * *'

"Q. 'This report is predicated upon the experiments conducted upon the animal?' A. 'That is correct.'

"Q. 'Made by Dr. Burby?' A. 'And myself.'

"Q. 'And Dr. Burby did the actual administration?'

"A. 'No. I administered to some dogs the application of oil in his presence.'

"Q. 'This purports to be his conclusion as a veterinarian too does it not?'

"A. 'Canine dermatology is the practice of the veterinarian, and naturally, he would sign as the veterinarian, and I as the scientist, the micrologist.'

* * *

"Mr. Gleason, the attorney for defendants-appellants: Q. 'I am going to ask you to refer to Defendants' Exhibit L for identification and ask you if that document refreshes your recollection as to facts observed by you in these clinical tests on animals as to the therapeutic value and power of the Colusa Natural Oil?'

"A. 'Yes.'

"Q. 'Please state briefly the facts observed by you in these clinical tests on this animal therapy as to the results of the use of Colusa Natural Oil and skin diseases of animals. And, Doctor, confine yourself to the facts that you know of your own knowledge and do not read any of the opinions if they are opinions of Dr. Burby.'

"Mr. Zirpoli, the assistant district attorney: 'I want to make this objection, your Honor. He is asked to testify as to the effect of the application of this oil, which calls for his opinion and conclusion as a veterinarian.'

"The Court: 'Objection sustained.'

"(Exception noted.)

"Mr. Gleason: Q. 'Doctor, in the practice of your profession as a pharmacologist and your work for these firms that you mentioned yesterday, including the Goodman Laboratories and the rest of them, as their consultant, do you in the practice of your profession resort to animal therapy to test the efficacy of drugs and preparations?'

"A. 'Yes.'

"Q. 'Is that a part of the ordinary practice of the ordinary pharmacologist?'

"A. 'That is the practice.'

"Q. 'I will ask you to state, Doctor, the facts that you observed, in your clinical examinations; that is to say, this animal therapy, from the use of Colusa Natural Oil upon the skin diseases of dogs and cats used in this animal therapy.'

"Mr. Zirpoli, the assistant district attorney: 'May it please the Court, I submit that the question is identical in different terms and objection is made exactly as it was made to the last question.'

"Mr. Doyle, attorney for defendant-appellant: 'This question asks for the knowledge of the witness.'

"The Court: 'The objection will be sustained.'

"It is apparent that the trial judge unduly limited the examination of the witness Dr. Von Hoover to the very great prejudice of the accused. The qualifications of Dr. Von Hoover were far more extensive than the average medical doctor or veterinarian possesses, and his familiarity with the materia medica, bacteriology, therapeutics, pharmacology and dermatology well qualified him to answer all of the questions which were put to him.

"In regard to the report which he had prepared, it does not appear that he was asked to do otherwise than use it to refresh his recollection as to his own acts in the testing of appellants' remedies. It is quite probable that the report contained matter as to which he could not testify, but this fact could not prevent its use in the limited manner suggested by appellants' counsel by their questions. There were other reports, some of them referring to experiments upon humans, which were similar in nature to the one above detailed, and their use by Dr. Von Hoover was prevented in like manner. This was error.

"It is claimed that 'The trial court committed prejudicial error in refusing to admit in evidence the testimonials offered by the defense.' It appears in count I of the information, and is incorporated in the second count by reference (we do not here consider the legal effect of the practice), that advertising matter within the package contained the following recitation: 'Colusa Natural Oil is credited by others with producing relatively as remarkable results as above pictured in relieving irritation of external Acne—Ezcema—Psoriasis—Athlete's Foot or Ring Worm—Poison Ivy— * * * Varicose Ulcers—Burns and Cuts.'

"It is claimed that defendants had a right to introduce written testimonials of many people to prove the truthfulness of this statement. It does not appear from defendants' recitation of the testimony that the government offered any proof upon this subject. This being true, there was no occasion for the truth to be established by the evidence. Aside from this, the introduction of letters received through the mail could not be received. The whole subject matter is immaterial.

"Under a single subhead appellants treat a number of assignments which we shall treat briefly.

"Appellants think they were prejudiced by the court's refusal to permit proof going to the truth of a certain statement contained in the advertising matter regarding the action of radium. The government had introduced testimony along this line—probably to show that the preparations do not contain radium. Appellants admit, however, that they have never claimed and do not claim that the preparations contain radium. In this circumstance any testimony relative to radium would be immaterial.

"Appellants complain that Dr. Tainter, an expert witness for the government, was permitted to testify as to the effect of Colusa Oil in poison oak cases and that Colusa Oil is an ordinary crude oil. This claim is without merit.

"Appellants complain that the attitude of the court was prejudicial. The court evidenced some lack of patience, as we read the record, against both sides. No objections were interposed. We think the impatience exhibited was not of a degree sufficient to constitute reversible error.

"They also complain of the cross-examination on immaterial matters. This amounts to nothing.

"In their brief under the subheading 'The court erred in refusing to permit appellants to prove various facts to show their good faith,' we have examined the claim and the argument and find no error.

"Appellants complain that the testimony of a Mr. Everett and of a Mr. Baumgartner was unduly limited upon objections that the questions call for the witnesses' conclusions. We agree but think the error inconsequential in the circumstances. It appears that counsel for defendants voluntarily abandoned the subject.

"Appellants sought to show they were wrongfully prevented from showing that the public was not misled by their advertisements. There is nothing to the point.

"Appellants claim that the third count is bad as being duplicitous. Upon authority of Weeks v. United States, 445 US 618, and United States v. Swift, 188 Fed. 92, we hold that the third count of the information is not duplicitous. In the latter cited case it is said, 'Duplicity in an indictment means the charging of more than one offense, not the charging of a single offense committed in more than one way. Duplicity may be applied only to the result charged, and not to the method of its attainment.'

"The government insists that there is substantial, even conclusive, evidence to support the conclusion that each package of drugs referred to in count III did not bear an accurate statement of the quantity of the contents in terms of weight or measure and that the verdict must stand as to this count upon that evidence alone. But the issue of guilt or innocence upon each separate count was submitted to the jury upon all of the material evidence relevant to each count. We have seen that reversible error was committed in the admission of evidence relative and material to count III and a verdict of guilty was returned. In these circumstances we cannot speculate as to whether the guilt was premised upon one or the other or upon all of the allegations contained in this count. Evidence was offered by appellants to show that any failure upon their parts to properly designate the amount of contents on labels used as charged in count III was accidental or by mistake of another. Upon objection that the evidence was immaterial, the court denied its reception.

"The instructions to the jury are in accord with the government's contention that no intent is necessary to a conviction upon the applicable statute and that no explanation of accident or mistake in any way affects the guilt or innocence of the accused. This subject is inadequately treated in the briefs, and since the judgments must be reversed upon the errors occurring during the examination of Dr. Von Hoover, we do not pass upon it.

"Reversed."

On October 7, 1943, the case was remanded for retrial and on December 10, 1943, the defendants entered pleas of nolo contendere. On December 23, 1943, the court imposed the same sentence upon the defendants that it had originally imposed.

1041. Misbranding of Vitaminerals VM No. 1, VM No. 150, VM 100, VM 120, and VM No. 204 Pneumatic Dilator. U. S. v. John Francis Gorman (Vitaminerals Co.). Plea of nolo contendere. Fine, $1,000 on 2 counts, and probation for 1 year on 3 counts. (F. D. C. No. 8791. Sample Nos. 81451–E, 81453–E to 81455–E, incl.)

On April 30, 1943, the United States attorney for the Southern District of California filed an information against John Francis Gorman, trading as the Vitaminerals Co., Los Angeles, Calif., alleging shipment on or about May 5, 1942, from the State of California into the State of Colorado of a quantity of the above-named products which were misbranded.

Examination of Vitaminerals VM No. 1 disclosed that this article was in the form of orange-colored tablets containing a large proportion of rhubarb root tissues together with Irish moss tissues (Chondrus), okra tissues, cranberry fruit tissues, parsley leaf tissues, and acid-insoluble material. It was alleged to be misbranded in that the statements in its labeling which created in the mind of the reader the impression that the article was a supplement in the dietary treatment of constipation; that the ingredient rhubarb root was a food; and that the article derived its physiological activity principally from concentrates and extracts from common vegetables used for food purposes, and from vitamins, were misleading since the article was not a supplement in the dietary treatment

of constipation, but was a laxative drug; the ingredient rhubarb root is not a food but is a drug; and the article did not derive its physiological activity principally from concentrates and extracts from common vegetables used for food purposes, and from vitamins, but derived its physiological activity principally from the plant drug rhubarb. It was alleged to be misbranded further (1) in that the statements in its labeling which represented and suggested that the article would be efficacious as a dietary treatment of constipation; that it possessed anti-infective value; that it would be an efficacious tonic treatment for the smooth muscle; that it would facilitate the changing of the colonic flora so as to reduce the colonic bacilli count and the resulting inflammation of the colonic mucosa; that it would promote peristaltic activity, and act practically in the treatment of constipation; that it would produce normal elimination; that it would be efficacious in the primary treatment of hemorrhoids; and that it would be efficacious in the secondary treatment of arthritis due to excess calcium, and arthritis due to systemic origin, colds, neuralgia, neurosis, obesity, and tonsilitis were false and misleading since the article would not be efficacious for the purposes recommended or accomplish the results claimed; (2) in that the name "Vitamineral" was misleading since the name suggested and created the impression in the mind of the reader that the article derived its physiological activity solely from vitamins and minerals and contained no other physiologically active ingredient, whereas the article contained rhubarb root, from which it derived its principal physiological activity; and (3) in that the statements in its labeling, "Ash (Mineral matters*) 22.20%," and "Mineral Matter includes: Calcium 2.18% Phorphorus 0.84% Potassium 1.15% Sodium 0.67% Magnesium 0.34% Chlorine 0.03% Sulphur 0.51% Manganese 0.0023% Iron 0.115% Copper 0.0013% Iodine 0.002%," were misleading since those statements suggested and created the impression in the mind of the reader that the article contained the minerals listed therein in amounts which, when taken in accordance with directions on the label, "Two to four tablets, one or two before breakfast and upon retiring," would furnish the minerals in quantities sufficient to contribute in an important respect to the daily requirements of the body for those minerals, whereas the article, when taken according to the directions, would not furnish such quantities of the minerals because the article contained inconsequential amounts of potassium, sodium, chlorine, magnesium, sulfur, manganese, and copper; and 4 tablets, the maximum amount recommended in the directions, would furnish less than one-thirtieth the minimum daily requirement of the body for phosphorus, less than one-tenth the minimum daily requirement for calcium, less than one-fifth the minimum daily requirement for iodine, and less than one-third the minimum daily requirement for iron.

Analysis of Vitaminerals VM No. 150 showed that it consisted of a brownish-yellow, perfumed ointment containing benzocaine. It was alleged to be misbranded (1) in that the statements in its labeling, "fortified with 8% Benzocaine Benzoate and Benzocaine," were false and misleading since the article contained no benzocaine benzoate and not more than 5.19 percent of benzocaine; (2) in that the statements in the labeling which represented and suggested that the article would be efficacious in the treatment of skin conditions, wounds, burns, hemorrhoids, ear infections, and tetany were false and misleading since the article would not be so efficacious; and (3) in that the name "Vitaminerals" was misleading since that name suggested and created the impression in the mind of the reader that the article derived its physiological activity solely from vitamins and minerals, whereas it derived its physiological activity from the physiologically active drug benzocaine.

Examination of the Pneumatic Dilator disclosed that this device was composed of 2 red rubber bulbs connected to each other through a one-way valve, and then through a foot of black rubber tubing to a steel tube partly covered with soft white rubber. This steel tube was equipped with a protective hard rubber or plastic cap at one end and a hard rubber or plastic, flanged shield near the other end in such a manner that the intervening portion of steel tubing was completely covered with the soft white rubber. This rubber covering could be inflated to a diameter of at least 2 inches by squeezing the first rubber bulb several times. The second rubber bulb produced a further inflation when compressed and was equipped with a release valve allowing for complete deflation when desired. The device was packed in a box containing 1 dozen white rubber finger cots and 1 jar of VM No. 150. The device was alleged to be misbranded because of the false and misleading statements in its labeling which represented and suggested that the device would be an efficacious and appropriate treatment for external and internal hemorrhoids, thrombotic type of simple varicosities with or without ulceration, prolapsed varicosities, benign

anal strictures, post-operative or post-injection strictures, spastic anal sphincters associated with inflammatory conditions of the intestinal tract, and with fissures, cryptitis, anal ulcers, anal excoriations, anal dermatosis, neurological conditions, genito-urinary conditions (prostatitis, uterine retroflexion, cervicitis, endometritis), pruritis and associated conditions, spastic constipation, also vaginismus, vaginodynia, prostatic disorders, spastic sphincters, proctitis, and other pathologies of the anorectal region; that the device was rapidly supplanting manual dilation, divulsion, and the use of solid or semi-solid dilators and digital prostatic massage; that the device would eliminate many unsatisfactory operations which are painful and injurious to inflamed tissues; that it would be efficacious to increase local metabolism and neuromuscular function; that it would bring about rapid healing, and would help progressively to re-establish normal physiological action in the rectum, anus, and contiguous structures; and that it would be an efficacious and appropriate treatment or prevention of nervous headaches, spastic colitis, low back pain or lumbago, biliousness, indigestion, dysmenorrhea, sciatica, lumbo-sacral soreness, nervousness, and neurasthenia.

Analysis of Vitaminerals VM 100 Vaginal Suppositories disclosed that the article consisted of plain gelatin capsules containing a mineral substance composed largely of sulfate, aluminum, acid-insoluble matter, and ferric iron, along with a small amount of ferrous iron and a possible trace of phosphate. It was alleged to be misbranded in that the statement in its labeling, "containing ferric sulfate, ferrous sulfate, and ferric phosphate," was false and misleading since it represented and suggested that the article contained significant amounts of ferric sulfate, ferrous sulfate, and ferric phosphate, and that it contained no aluminum sulfate, whereas the article contained no ferric sulfate or ferrous sulfate, and an insignificant proportion of ferric phosphate, and did contain a material amount of aluminum sulfate. It was alleged to be misbranded further because of false and misleading statements in its labeling which represented and suggested that the article would be efficacious to produce toning and granulation of new tissues; that it would cause pathological tissue to slough with every indication of a natural reaction, leaving no scar tissue; that it was an efficacious and appropriate treatment for endocervicitis, endometritis, vaginitis, polypus–vaginal and uterine, cysts, leucorrhea, dysmenorrhea, and amenorrhea; that it would be efficacious in the treatment of abnormal tissue growths; that it would be an efficacious and appropriate treatment in cases of hemorrhage; and that it was an efficacious and appropriate primary treatment for uterine cramps, dementia, and deficient menstruation.

Analysis of Vitaminerals VM 120 disclosed that it consisted of an acidic, aqueous solution containing sulfate, aluminum, glycerin, ferric iron, and a trace of ferrous iron. It was alleged to be misbranded in that the statements in its labeling, "An Astringent and detergent liquid concentrate containing Ferric Sulphate derived from natural sources," and "Ferric Sulphate, Ferrous Sulphate and Ferric Phosphate," were false and misleading, since those statements represented and suggested and created the impression in the mind of the reader that the article contained ferric phosphate and derived its astringent properties solely from ferric sulfate, ferrous sulfate and ferric phosphate, whereas the article contained little, if any, ferric phosphate, and did not derive its astringent properties solely from ferric sulfate, ferrous sulfate and ferric phosphate, but did contain a large amount of aluminum sulfate, from which its astringent properties were largely derived. It was alleged to be misbranded further because of false and misleading statements in its labeling which represented and suggested that the article would be efficacious to build tone and resistance to infection; that it would produce results in various colon disorders, and would combat colitis and other complicated diseases; that it would be efficacious in the treatment of stomatitis, tonsilitis, and kindred infections of the throat, pyorrhea and trench mouth; that it would be efficacious as a nasal douche in the treatment of nasal congestion, head colds, sinus, and like infections; that it would be efficacious as an eye wash to produce a soothing and healing action on the delicate membrane of the eye; that it would be efficacious in the prophylaxis of pterygium and in the treatment of local infections of the ear canal, cuts, sores, open wounds, ulcers, burns, and similar conditions, indicated by the abbreviation "etc."; that it would be efficacious in relieving inflammation, reducing pain, and restoring normal tissues in hemorrhoid cases, and would bring prompt relief and promote rapid healing in gastric ulcers; that the article would serve as a general body tonic; that it would be efficacious when administered orally in the primary treatment of albuminuria, anemia, cramps, diarrhea, enteritis, excessive men-

struation, gastritis, uterine hemorrhage, influenza, intestinal disorders, kidney disorders, kidney inflammation, disorders of the liver, such as catarrhal gall ducts, cirrhosis (alcoholic) and enlargement, malaria, nausea and vomiting, orchitis, lack of resistance, tentany, duodenal, gastric, stomach, and peptic ulcers, intestinal ulcers, and tape and helminth worms; that it would be efficacious when used topically in the primary treatment of acne, boils, exzema, empyema, and hives; that the article would be efficacious in the primary treatment by pack method of hemorrhages, including uterine hemorrhages; that it would be efficacious, when used as directed, in the primary treatment of ameba, amenorrhea, calcium in lenses, catarrh, corneal ulceration, uterine cramps, cystitis, dysmenorrhea, ear infections, endocervicitis, endometritis, eye infections, fistula, hemeralopia, impetigo, keratomalacia, laryngitis, leg ulcers, leukorrhea, excessive, deficient and painful mentruation, miscarriage, opthalmia, vaginal and uterine polypus, rectal polypus, prostatitis, proctitis, psoriasis, respiratory infections, shingles, skin disorders, sty, loose teeth, uterine prolapse, vaginitis, varicose ulcers, varicose veins, and xerophthalmia; and that it would be efficacious, when used orally, in the secondary treatment of acidosis, alcoholic neuritis, ameba, angina pectoris, asthenia, asthma, boils, Bright's disease, calculi of the bladder and kidneys, faulty digestion, eczema, gall bladder inflammation, gallstones, gastro-intestinal disturbances, hay fever, hemophilia, biliary stasis of the liver, engorgement and jaundice of the liver, lymph infections, mal-petit-grand, malnutrition, nausea and vomiting of pregnancy, neurasthenia, old age, septicemia, and tuberculosis.

All of the articles were alleged to be misbranded further in that the statement in their labeling, "We hereby guarantee that all Vitamineral products listed herein are not adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act of June 25, 1938," was false and misleading, since the articles were misbranded within the meaning of that Act.

The information alleged in count 1 that the product "Vitaminerals VM No. 1" was also misbranded under the provisions of the law applicable to foods, reported in notices of judgment on foods.

On September 27, 1943, the defendant having entered a plea on nolo contendere, the court imposed fines of $500 on count 1 of the information, which involved charges against the Vitaminerals VM No. 1 both as a food and a drug, and $500 on count 3, which involved the drug Vitaminerals VM No. 150, and placed the defendant on probation with respect to the remaining 3 counts which involved the other products.

1042. Misbranding of Cel-Bio Mineral Tablets, Nos. 1 to 12, incl. U. S. v. Fred N. Haas (Cel-Bio Mineral Food Co.). Plea of guilty. Fine, $90 and costs. (F. D. C. No. 8790. Sample Nos. 73341–E to 73351–E, incl., 73558–E to 73564–E, incl.)

On May 12, 1943, the United States attorney for the District of Nebraska filed an information against Fred N. Haas, trading as the Cel-Bio Mineral Food Co., Omaha, Nebr., alleging that he had shipped, on or about May 7 and 8, 1942, from the State of Nebraska into the State of Iowa, quantities of Cel-Bio Mineral Tablets Nos. 2, 3, 4, 5, 8, 9, and 11, which were misbranded; and that within the period from on or about October 1 to 22, 1941, the defendant had repacked and relabeled quantities of Cel-Bio Mineral Tablets Nos. 1, 2, and 3, and Nos. 5 to 12, inclusive, while they were being held for sale after shipment to him in interstate commerce from the State of Illinois into the State of Nebraska, which acts by the defendant resulted in the misbranding of the products.

Analysis of the No. 9 Tablets showed that they consisted essentially of lactose containing a minute amount of sodium chloride. They were alleged to be misbranded because of false and misleading statements in their labeling which represented and suggested that the tablets would enable one to wake up in the morning with pep; and that they were efficacious in the cure, mitigation, treatment, or prevention of sneezing, water discharge from the eyes, nose, or any part of the body, hay fever, rose fever, vomiting of water and mucus, water blisters on the skin, diarrhea, slimy, transparent stools, inflammation of the eyes, a salty taste in the mouth, periodical pains, drug poisonings, drug habits, painful swellings of the ankles or legs, dropsy, dandruff, dry skin, cold sores, and catarrh with watery discharge.

Analysis of the No. 8 Tablets showed that they consisted essentially of lactose containing a minute amount of magnesium phosphate. They were alleged to be misbranded because of false and misleading statements in their labeling which represented and suggested that the tablets would relax the nerves, relieve pain

due to mineral deficiencies or otherwise, aid in the formation of white fibers of the nerves and muscles, and overcome contraction of such fibers; and that they would be efficacious in the cure, mitigation, treatment, or prevention of intense pains, spasms, cramps, shooting pains, spasmodic pains, pains relieved by heat and aggravated by cold, shaking of the body, twitching of the eyelids, squinting, contracted pupils, sparks or colors before the eyes, dullness of sight from weakness of the optic nerves, spasmodic stammering, sensitive teeth, toothache, constricted feeling in the throat, hiccough, lockjaw, convulsions, epilepsy, St. Vitus dance, colic, menstrual colic, and whooping cough.

Analysis of the No. 4 Tablets showed that they consisted essentially of lactose containing a minute amount of iron phosphate. They were alleged to be misbranded because of false and misleading statements in their labeling which represented and suggested that the tablets would be efficacious in the cure, mitigation, treatment, or prevention of fever delirium, inflammation, congestion, soreness to touch or pressure, throbbing pains, pains made worse by movement, accidental injuries, cuts, bruises, burns, hemorrhage, nose bleed, dizziness caused by stooping, a rush of blood to the head, flushed face, high blood pressure, thin blood, slow digestion, belching, diphtheria, pneumonia, smallpox, chicken pox, measles, scarlet fever, tonsilitis, quinsy, pleurisy, rheumatism, and bleeding piles.

Analysis of the No. 2 Tablets showed that they consisted essentially of lactose containing a minute amount of calcium phosphate. They were alleged to be misbranded because of false and misleading statements in their labeling which represented and suggested that they would be efficacious to clear the complexion, to enable one to enjoy health and show it, and to bring about normal action of every fluid, organ, and tissue in the body, including the brain, heart, lungs, arteries, veins, bones, teeth, glands, skin, blood, and organs of digestion and assimilation; and that they would be efficacious in the cure, mitigation, treatment, or prevention of poor circulation, cold or numbness of the hands and feet, numbness in any part of the body, decaying teeth, all bone diseases, sluggish glands, sallow or dirty appearance of the skin, freckles, slow digestion, gas on the stomach ordinarily relieved by belching, the feeling of a lump in the stomach after eating, pain that becomes worse at night, aching bones, headache from wearing a hat, poor memory, colds from drafts, albumin discharge from any part of the body, albumin discharge in the urine (Bright's disease), teething disorders, peevish and fretful children, and too early menstruation in young girls.

Analysis of the No. 11 Tablets showed that they consisted essentially of lactose containing a minute amount of sodium sulfate. They were alleged to be misbranded because of false and misleading statements in their labeling which represented and suggested that the tablets would keep the body bile under control, rid one of a yellow complexion, maintain the right proportions of water in all tissues, and control bile function; and that they would be efficacious in the cure, mitigation, treatment, or prevention of a bitter taste in the mouth, vomiting, yellow color of the skin or eyes, liver spots, severe pains in the liver region, sick headache with vomiting, dark, greenish stools, gallstones, dropsy, jaundice, diabetes, giddiness, violent pains at the base of the brain, erysipelas, excessive secretion of urine, sandy deposits in the urine, gravel, kidney stones, asthma, a feeling of pressure and uneasiness in the heart region, ague, and chills with fever.

Analysis of the No. 5 Tablets showed that they consisted essentially of lactose containing a minute amount of potassium chloride. They were alleged to be misbranded because of false and misleading statements in their labeling which represented and suggested that they would keep the blood stream balanced and thus would enable the user to avoid surgical operations; and that they would be efficacious in the cure, mitigation, treatment, or prevention of swollen glands, swelling with pain or soreness in any part of the body, coated tongue, thick white or gray discharge from any part of the body, earache with swollen glands and coated tongue, swollen tonsils, deafness from swelling or thickening of the drum, colds with thick white discharge, diphtheria, pneumonia, smallpox, chicken pox, measles, scarlet fever, mumps, tonsilitis, burns, and scalds.

Analysis of the No. 3 Tablets showed that they consisted essentially of lactose containing a minute amount of calcium sulfate. They were alleged to be misbranded because of false and misleading statements in their labeling which represented and suggested that the tablets would keep the body clean within, and would eliminate pus or filth from the body tissues and give one a healthy skin; and that they would be efficacious in the cure, mitigation, treatment, or pre-

vention of pimples, cuts or sores slow to heal, pus or matter from boils, carbuncles, ulcers, or abscesses on any part of the body, catarrh with a yellow pus discharge, lung trouble with thick yellow pus, cases of accidental injury which fail to heal, blood and pus or matter in the stools, inflamed eyes or gland trouble with pus discharge, gum boils, inflammation of the bladder with pus in the urine, and crust or scald head of children.

Analysis of the No. 12 Tablets showed that they consisted essentially of lactose containing a minute amount of silica. They were alleged to be misbranded because of false and misleading statements in their labeling which represented and suggested that they would keep the blood stream clean, enable one to avoid surgical operations, eliminate pus from the body, and build hair, nails, skin, nerves, and bone tissue; and that they would be efficacious in the cure, mitigation, treatment, or prevention of falling hair, thin or brittle nails, unhealthy skin, pus discharge from any part or organ of the body, night sweats, sweating feet and armpits, the pus stage of boils, felons, ulcers, carbuncles, abscesses, fistula, eruptions on the face, tonsilitis characterized by pus formation, sties on the eyelids, a sore or sensitive scalp, pus in the urine, chronic gonorrhea, slow mental action, and heavy, pulling pain.

Analysis of the No. 10 Tablets showed them to consist essentially of lactose containing a minute amount of sodium phosphate. They were alleged to be misbranded because of false and misleading statements in their labeling which represented and suggested that they would prevent colds, overcome or control body acidity, and maintain a proper balance in the blood stream; and that they were efficacious in the cure, mitigation, treatment, or prevention of sour vomiting, belching, frequent head colds, stomach trouble with acidity, heartburn, indigestion, a red and blotched face, worms, canker sores, grinding of the teeth during sleep, headache, sick headache with vomiting, eyelids glued together in the morning, diarrhea with green stools, itching of the skin, and ulcerations.

Analysis of the No. 6 Tablets showed that they consisted essentially of lactose containing a minute amount of potassimu phosphate. They were alleged to be misbranded because of false and misleading statements in their labeling which represented and suggested that they were a brain or nerve food and would give one a clear brain, calm the nerves, and bring happiness; and that they would be efficacious in the cure, mitigation, treatment, or prevention of nervous dread, sleeplessness from nervous cause, worry or excitement, conditions aggravated by noise, brain fag from overwork, loss of memory, hysteria, paralysis, shortness of breath, palpitation of the heart, aches and pains relieved by gentle movement, conditions aggravated by mental exertion, a "gone" sensation in the stomach, hunger after eating, crying moods, cross, fretful children, bashfulness, despondency, worry, foul breath, a foul taste in the mouth, sudden dizzy spells, difficult speech, and the feeling of a lump in the throat.

Analysis of the No. 1 Tablets showed that they consisted essentially of lactose containing a minute amount of calcium fluoride. They were alleged to be misbranded because of false and misleading statements in their labeling which represented and suggested that they would be efficacious in the building of vitality and would make one feel and look younger; that they would bring about perfect muscular action of the vital organs, including the heart, stomach, arteries, veins, and intestines; that they would aid in the formation of enamel on the teeth, the covering of the bones, and the elastic fiber of all muscular tissues; and that they would be efficacious in the cure, mitigation, treatment, or prevention of flabby muscles, double chin, flabby, enlarged abdomen, flabby heart, flabby valves (leakage of the heart), falling of the womb, piles, varicose veins, ruptures, flabby bowels, constipation, flabby arteries (low blood pressure), hardening of the arteries (high blood pressure), horny, rough skin, rough, thin, or brittle enamel on the teeth, a tired, "no-pep" feeling, a general bearing down feeling, cataract of the eye, and enlarged glands.

Analysis of the No. 7 Tablets showed that they consisted essentially of lactose containing a minute amount of potassium sulphate. They were alleged to be misbranded because of false and misleading statements in their labeling which represented and suggested that the tablets would keep the pores of the skin healthy, promote elimination of waste through the skin, and carry oxygen and nourishment to the skin and scalp; and they would be efficacious in the cure, mitigation, treatment, or prevention of fever, chronic catarrh, shifting pains, hot and dry skin, coated tongue, discharge from a mucus surface, eczema, erysipelas, ivy poisoning, nettle rash, dandruff, whooping cough, pneumonia, yellow scales on the skin, eruption of measles, smallpox, and scarlet fever, and skin trouble with sticky, yellowish secretions.

The articles were alleged to be misbranded further because of false and misleading statements which represented and suggested, in the case of all the various products, that the tablets were guaranteed under the Food and Drug Act of 1906, and, in the case of portions, that they had been repacked in accordance with the provisions of the act of Congress known as the Federal Food, Drug, and Cosmetic Act of 1938 and complied in all respects with the requirements of that Act.

On June 3, 1943, the defendant having entered a plea of guilty, the court imposed a fine of $5 on each of the 18 counts, totaling $90 plus costs.

1043. Misbranding of Balm and Gilead Herb Tonic, Manning's Asthma Plaster, Asthma Tea, D. R. Manning Asthma Salve, Manning's Princess Gaynell Hair Tonic, D. R. Manning Throat Gargle, D. R. Manning Antiseptic Douch Powder, Manning's Whoa Liniment, an article labeled "For Nervous Run Down Women," Blood Tonic, and Blood and Liver Capsules. U. S. v. Donald R. Manning (Manning Herb House). Plea of guilty. Defendant placed on probation for 3 years. (F. D. C. No. 8781. Sample Nos. 80081-E to 80091-E, incl.)

On March 18, 1943, the United States attorney for the Northern District of Alabama filed an information against Donald R. Manning, trading as the Manning Herb House, Bessemer, Ala., alleging shipment on or about March 30, 1942, from the State of Alabama into the State of Ohio of quantities of the above-named products which were misbranded.

Analysis of the Balm and Gilead Herb Tonic showed that it contained plant drug extractives (no alkaloids), a small amount of gum resin, reducing sugar, and water, and possessed a balsam-like odor. It was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that it would be efficacious in the cure, mitigation, treatment, or prevention of asthma cough and chronic cough; and that it would be efficacious as a tonic for persons afflicted with asthma cough or chronic cough were false and misleading since it would not be efficacious for these purposes.

Analysis of Manning's Asthma Plaster showed that it consisted essentially of dry ground mustard and ground black pepper. It was alleged to be misbranded in that the statement "Asthma Plaster," borne on its label, was false and misleading since it represented and suggested that the article would be efficacious in the cure, mitigation, treatment, or prevention of asthma, whereas it would not be so efficacious. It was alleged to be misbranded further in that it was in package form and did not bear a label containing an accurate statement of the quantity of the contents, since the label of the article bore no statement of the quantity of the contents; and in that it was not designated by a name recognized in an official compendium; and it was fabricated from two or more ingredients and the label on its package failed to bear a statement of the common or usual name of each active ingredient.

Analysis of the Asthma Tea showed that it consisted essentially of roughly ground plant material. It was alleged to be misbranded in that the statement "Asthma Tea," borne on its label, was false and misleading since it represented and suggested that the article would be efficacious in the cure, mitigation, treatment, or prevention of asthma, whereas it would not be so efficacious. It was alleged to be misbranded further in that it was in package form and its label failed to bear an accurate statement of the quantity of the contents, since the package was labeled "Contents 3 Ozs.," whereas it contained materially less than 3 ounces of the article, i. e., 1.70 ounces net.

Analysis of the D. R. Manning Asthma Salve showed that it consisted essentially of a small amount of volatile oils, including menthol, eucalyptol, and camphor, incorporated in a petrolatum base. It was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that the article would be efficacious in the cure, mitigation, treatment, or prevention of head colds, headache, catarrh, hay fever, asthma, and sinus were false and misleading since the article would not be efficacious for those purposes.

Analysis of Manning's Princess Gaynell Hair Tonic showed that it contained a small amount of plant debris and bore a moderate odor of cardamon or lavender. It was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that it would be efficacious as a food or fertilizer for the hair, would feed the roots of the hair, and would act as a tonic for the hair were false and misleading since it would not be efficacious for those purposes.

Analysis of the D. R. Manning Throat Gargle showed that it consisted essentially of plant material, probably of citrus and pineapple origin, and

water, preserved with sodium benzoate. It was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that it would be efficacious in the cure, mitigation, treatment, or prevention of sore throat, hoarseness, and inflammaion of the throat; that it would be efficacious as a tonic; and that it would remove goiters, were false and misleading since the article would not be efficacious for the purposes recommended.

Analysis of the D. R. Manning Antiseptic Douch Powder showed that it consisted essentially of boric acid and oxyquinoline sulfate in the respective proportions of about four to one. Bacteriological examination showed that the article was not antiseptic when diluted according to directions. It was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that the article, in the dilutions recommended, was an antiseptic and would be efficacious as a douche in maintaining feminine hygiene were false and misleading since the article, in the dilutions recommended, was not an antiseptic within the meaning of the law, and would not be efficacious for the purpose recommended.

Analysis of the Whoa Liniment showed that it consisted essentially of an inflammable hydrocarbon capable of ignition with red hot metal, and that it contained mustard oil and camphor. It was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that the article would be efficacious in the cure, mitigation, treatment, or prevention of rheumatism, sciatica, lumbago, arthritis, hurts, pains, aches, head and back aches, cuts, and sores; and that it would cause aches and pains to disappear, were false and misleading since it would not be efficacious for those purposes.

Analysis of the article "For Nervous Run Down Women" showed that it consisted essentially of a small amount of plant debris, water-soluble plant extractives, and water. It was alleged to be misbranded in that the statement "For Nervous Run Down Women," appearing in its labeling, was false and misleading since it represented and suggested that the article would be efficacious in the cure, mitigation, treatment, or prevention of nervous, run-down conditions in women, whereas it would not be efficacious for those conditions.

Analysis of the Blood Tonic showed that it contained plant debris, water-soluble plant extractives, and water, and possessed a foul odor suggestive of burdock or Jimson weed. It was alleged to be misbranded in that the statement in its labeling, "Blood Tonic," was false and misleading since it represented and suggested that the article was a tonic for the blood, whereas it was not.

Analysis of the Blood and Liver Capsules showed that they contained mercury (about 10 percent) and black pepper.

The article was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that it would be efficacious in the cure, mitigation, treatment, or prevention of diseases or disorders of the blood, liver, stomach, and bowels were false and misleading since the article would not be efficacious for those purposes. It was alleged to be misbranded further in that it was in package form and its label failed to bear an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, since the envelope containing the article bore the statement "Quantity 44 Capsules," whereas the envelope contained 14 capsules.

On June 30, 1943, the defendant having entered a plea of guilty, the court placed him on probation for a period of 3 years.

1044. Misbranding of Rheumatox. U. S. v. Arnold Nydegger (Rheumatox Co.). Plea of guilty. Fine, $250. (F. D. C. No. 8737. Sample Nos. 91680–E, 1406–F.)

On December 31, 1942, the United States attorney for the Northern District of Ohio filed an information against Arnold Nydegger, trading as the Rheumatox Co., Cleveland, Ohio, alleging shipment on or about April 20 and July 15, 1942, from the State of Ohio into the State of Michigan of quantities of Rheumatox.

Analysis of this article showed that is consisted essentially of an aqueous solution of sodium salicylate, methenamine, potassium citrate, potassium iodide, emodin-bearing drugs, and a small amount of alcohol.

The article was alleged to be misbranded in that the name under which it was sold, "Rheumatox," and the word "Rheumatox" in the firm name under which the defendant traded, were misleading since the name suggested and created in the mind of the reader the impression that the article would be efficacious in the cure, mitigation, treatment, or prevention of rheumatism, whereas it would not be so efficacious. It was alleged to be misbranded further because of false and misleading statements in its labeling which represented and

suggested that excess uric acid commonly causes arthritis, neuritis, lumbago, sciatica, rheumatic pains, and gout; that the article would neutralize and eliminate deposits or uric acid; that it would break down deposits of uric acid crystalline salts and cleanse the blood stream; and that it would be efficacious in the cure, mitigation, treatment, or prevention of arthritis, neuritis, lumbago, sciatica, rheumatic pains, and gout. It was alleged also to be misbranded in that it was not designated solely by a name recognized in an official compendium, and it was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient, since the article contained the active ingredient potassium iodide, and its label failed to bear a statement that the article contained that ingredient.

On June 22, 1943, the defendant entered a plea of guilty and on July 3, 1943, the court imposed a fine of $250.

1045. Misbranding of Nakamo Bell Tablets. U. S. v. 5¾ Dozen Packages of Nakamo Bell Tablets. Default decree of condemnation and destruction. (F. D. C. No. 9503. Sample No. 44607–F.)

On March 9, 1943, the United States attorney for the District of New Jersey filed a libel against 5¾ dozen packages of the above-named product at Newark, N. J., alleging that the article had been shipped on or about November 20, 1942, from Orangeburg, N. Y., by the Hollings-Smith Co.; and charging that it was misbranded.

Examination showed that the article was a tablet which consisted essentially of 2 grains of ammonium chloride, 3 grains of sodium chloride, and 1 grain of potassium chloride.

It was alleged to be misbranded because of false and misleading statements in the labeling regarding the efficacy of the article in the treatment of hay fever, sinus, asthma, and colds.

On June 21, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1046. Misbranding of Kaps Colloidal Iodized Sulphur. U. S. v. 12 Packages of Kaps Colloidal Iodized Sulphur. Decree of condemnation and destruction. (F. D. C. No. 9042. Sample No. 24524–F.)

On December 18, 1942, the United States attorney for the District of Maryland filed a libel against 12 packages of Kaps Colloidal Iodized Sulphur at Baltimore, Md., alleging that the article had been shipped from New York, N. Y., on or about June 5 and August 27, 1942, by the Jamco Co.; and charging that it was misbranded. The article was labeled in part: "C. I. S. Kaps Colloidal Iodized Sulphur."

Examination showed that the article consisted of capsules containing mineral oil, sugar, small amounts of sulfur, and an iodide.

The article was alleged to be misbranded in that the statement, "for use as an aid in the relief of Arthritis due to sulphur deficiency," was false and misleading since such statement represented and suggested that the article would be effective in the treatment of arthritis, whereas it would not be so effective.

On January 21, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1047. Misbranding of Pyrozide Tooth Powder. U. S. v. 282 Packages of Pyrozide Tooth Powder. Consent decree of condemnation. Product ordered delivered to a charitable institution. (F. D. C. No. 8902. Sample Nos. 18812–F, 18813–F.)

Examination of this product showed that it consisted essentially of calcium carbonate with smaller quantities of magnesium carbonate, powdered cinchona bark, salicylic acid, soap, and flavoring materials. It was short of the declared weight.

On or about November 30, 1942, the United States attorney for the Southern District of New York filed a libel against 282 packages of Pyrozide Tooth Powder at New York, N. Y., alleging that the article had been shipped on or about August 3 and October 22, 1942, by the Web Distributing Co. from Newark, N. J.; and charging that it was misbranded.

It was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that it was effective in the treatment of pyorrhea, gingivitis, trench mouth, and all other diseases of the oral tissue were false and misleading since the article was not effective in the treatment of those diseases; and in that it was in package form and its label failed to bear an accurate statement of the quantity of the contents.

On June 25, 1943, the Web Distributing Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and it was ordered that the product be delivered for the use of a charitable institution, and that costs be assessed against the claimant.

1048. Misbranding of Cuban honey. U. S. v. 38 Jars and 284 Packages of Honey. Decrees of condemnation. Portion of product ordered destroyed and remainder ordered sold, upon adoption of safeguards to insure its use in compliance with the law. (F. D. C. Nos. 8170, 8371. Sample Nos. 1116–F, 1117–F, 5901–F.)

On August 21 and September 28, 1942, the United States attorneys for the Eastern District of Missouri and the Northern District of Illinois filed libels against 25 $1.00-size, 7 $2.00-size, and 6 $3.75-size jars of honey at St. Louis, Mo., and 141 9-ounce, 81 22½-ounce, 56 48-ounce, 3 96-ounce, and 3 1-gallon packages of honey at Chicago, Ill., alleging that the article had been shipped in interstate commerce on or about June 16, July 18, and August 29, 1942, from Lansing, Mich., by Cuban Honey, Inc.; and charging that it was misbranded. The article was labeled in part: "El Aguinaldo Cuban Honey."

Analysis of a sample of the article showed that it consisted of honey, and that the mineral matter therein amounted to approximately one-sixth of one percent.

The lot at Chicago was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that the product would constitute a remedy for sick and wounded soldiers; and that it provided a significant portion of minerals and constituted an adequate treatment for digestive disorders, bronchial asthma, bronchitis, asthma, bronchial pneumonia, coughs, sinus conditions, hay fever, and stomach ulcers were false and misleading since it would not constitute a remedy for sick and wounded soldiers nor be an adequate treatment for the condition described; and it did not provide a significant portion of minerals.

The lot at St. Louis was alleged to be misbranded because of false and misleading statements appearing in its labeling which represented and suggested that the product constituted a remedy for sick and wounded soldiers; that it was valued for its medicinal properties; that it played an important part in the preservation of zestful health for those who were well and in restoring health to those who were ill; that it differed in a material respect from domestic honey; that, when used in the place of other sweets, it would cause children to thrive; that it constituted a source of vital energy and was a great help in the heavy daily battle of life; that it would aid nature in building and maintaining health; that, when taken as directed, it possessed laxative qualities; that it was a relaxing food; that it would aid in more normal action of the digestive system; that it would be retained by those whose digestion was impaired and who have difficulty in retaining food; that it would soothe tired nerves and aid in preventing sleepless nights; that it defied chemical analysis; that it provided the necessary mineral salts; that it contained a significant proportion of minerals; that it was more easily retained in the stomachs of children than were other foods suitable for them; that it was a substitute for cod liver oil and orange juice; that, when used as directed, it would cause an increase in weight in children not caused by other common foods; that it would cause a decrease in restlessness and distress after feeding; and that it was efficacious in cases of rickets and malnutrition. The article did not differ in a material respect from domestic honey; it had not defied chemical analysis; it did not contain a significant proportion of minerals; it was not a substitute for cod liver oil and orange juice; and it would not be efficacious for the purposes recommended, or accomplish the results claimed. Both lots were alleged to be misbranded further in that the following statements appearing in the labeling of the lot at St. Louis, "Analysis ____%____ Water 18.53, Invert Sugars 71.01, Sucrose .83, Ash .25, Dextrine 2.39, Undetermined 6.99, Alkaloids None," and "Analysis of Ash ____%____ Silicon 4.78, Iron .88, Calcium 3.67, Magnesium 1.18, Sodium 14.12, Potassium 48.47, Phosphorous .78, Sulphur .97, Chlorine 9.87, Undetermined 15.27," and substantially the same statements in the labeling of the lot at Chicago, were misleading since those statements failed to reveal that the article consisted essentially of a variety of sugars, and that the other constituents named, including the various mineral elements mentioned, were present in the article in so small a proportion as to be negligible.

The article was also alleged to be misbranded under the provisions of the law applicable to foods as reported in the notices of judgment on foods, No. 5797.

On December 7, 1942, and January 6, 1943, no claimant having appeared, judgments of condemnation were entered and it was ordered that the lot at Chicago be destroyed and that the lot at St. Louis be sold to the person or corporation offering the highest bid and adopting such safeguards as might be recommended by the Federal Security Agency against use of the product in violation of the law.

DRUGS FOR VETERINARY USE*

1049. Misbranding of Ferro-Tone. U. S. v. Burton H. Corbett (Burton H. Corbett and Co.). Plea of nolo contendere. Fine, $300. (F. D. C. No. 9613. Sample Nos. 81542–E, 81544–E, 15341–F, 15342–F.)

The labeling of this product bore false and misleading statements in regard to its ingredients and its therapeutic and antiseptic properties. Samples of a portion of the product were short weight.

On May 4, 1943, the United States attorney for the District of Colorado filed an information against Burton H. Corbett, trading as Burton H. Corbett and Co., Denver, Colo., alleging the shipment of a number of cans of Ferro-Tone from the State of Colorado into the States of Nebraska and Wisconsin, on or about January 28 and February 2, 1942, respectively, and into the States of Iowa and Wisconsin on or about November 30, 1942.

Analyses of samples from the January and February shipments disclosed that they consisted essentially of ferrous sulfate and salt, with smaller proportions of powdered charcoal, powdered bone, powdered linseed, iron ferrocyanide, and a trace of sulfur; and that very little, if any, sodium bicarbonate, calcium carbonate, zinc phenolsulfonate, and potassium iodide were present. Analyses of samples from the November shipments disclosed that they consisted essentially of sodium chloride and ferrous sulfate with traces of sulfur and potassium iodide. Charcoal, ferrocyanide, carbonate, zinc, phosphate, and phenolsulfonate were not detected.

The article was alleged to be misbranded (1) in that the name "Ferro-Tone," borne on the label, was misleading since that name suggested and created in the mind of the reader the impression that the article was an iron tonic—that, when fed to livestock as directed it would be efficacious as a tonic in those conditions in which administration of iron to livestock is indicated, whereas it was not an iron tonic and it would not be efficacious as a tonic in those conditions described; and (2) in that the name "Ferro-Tone," the design of a sheep, a cow, a horse, and a hog, and the statements, "For Hogs, Cattle, Sheep and Horses," and "Directions For Cattle, Horses, Mules and Sheep: Thoroughly mix with shovel, hoe or paddle One Pound of Ferro-Tone with fifty pounds of fine or No. 4 Salt. * * * For Hogs and Pigs: Thoroughly mix with shovel, hoe or paddle, one quarter pound of Ferro-Tone with each fifty pounds of swill, wet or dry mash * * *," borne on the label, were false and misleading since the statements and design represented and suggested that the article, when used as directed, would be efficacious as an iron tonic for hogs, pigs, cattle, sheep, horses and mules, whereas it would not be so efficacious when used as directed. It was alleged to be misbranded further (1) in that the statement, "An Iron and Mineral Compound to be added to the regular rations, to supply certain minerals lacking in many feeds," borne on the label, was false and misleading since it represented and suggested that the article, when used as directed, would furnish a significant amount of iron and other minerals, whereas when used as directed, it would not furnish a significant amount of iron or any other mineral with the exception of salt; and (2) in that the statement in its labeling, "Contains: Ferrocyanide of Iron, Iron Sulphate, Sulphur, Phosphate of Lime, Sodium Bicarbonate, Calcium Carbonate, Sodium Chloride, Charcoal, Zinc Phenolsulphonate, Potassium Iodide, and Oil of Anise," was false and misleading since it represented and suggested and created in the mind of the reader the impression that the article contained appreciable amounts of each of the ingredients named in the statement, whereas it did not contain appreciable amounts of those ingredients, other than iron sulfate and salt; and its labeling failed to reveal the fact that none of the ingredients listed, when used as directed, would be active with the exception of the salt. It was alleged to be misbranded also (1) in that the statement in its labeling, "For Hogs and Pigs: Thoroughly mix * * * one quarter pound of Ferro-Tone with each fifty pounds of swill, wet or dry mash, and continue its use until the desired results are produced," were misleading since it created the impression that use of the article would result

*See also Nos. 1009, 1010.

in improvement in the health and thriftiness of hogs and pigs, whereas the article would not produce such results or any known desired results; and (2) in that certain statements in its labeling which represented and suggested that it contained an appreciable amount of zinc and that, when used as directed, it would act as an antiseptic and astringent because of its content of zinc phenolsulfonate; that, when used as directed, it contained significant amounts of iron which would correct deficiencies in the rations, feeds, or grazing lands which had caused anemia in animals; that, when used as directed, it would increase the hemoglobin content of the blood; and that it contained a significant amount of iodide and, when used as directed, would be effective in correcting iodine deficiencies such as goiter in animals were false and misleading since it contained an insignificant amount of zinc and iodide, and, when used as directed, would not act as an antiseptic or astringent or accomplish the results claimed.

The November shipments of the article were alleged to be misbranded further in that the statement on the label, "Eight Pounds Net Wt.," was false and misleading since each of the cans containing the article did not contain 8 pounds net weight but contained a materially smaller amount; and in that the article was in package form and did not bear a label containing an accurate statement of the quantity of the contents.

On June 11, 1943, the defendant entered a plea of nolo contendere and the court imposed a fine of $75 on each of the 4 counts, a total fine of $300.

1050. Misbranding of Mutual Compound. U. S. v. Joseph C. Winslow and Stephen R. Winslow (Mutual Products Co.). Plea of guilty. Fine, $100. (F. D. C. No. 8752. Sample No. 76895–E.)

On February 6, 1943, the United States attorney for the District of Minnesota filed an information against Joseph C. Winslow and Stephen R. Winslow, trading as the Mutual Products Co., Minneapolis, Minn., alleging shipment on or about March 3, 1942, from the State of Minnesota into the State of Wisconsin of a quantity of a drug known as Mutual Compound which was misbranded.

Analysis of the article showed that it consisted essentially of a mixture of wheat, corn, and oat products, dry milk, small amounts of salt, sugar, reducing sugars, yeast, iodide, calcium, iron, phosphate compounds, anise, and resinous material.

The article was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that it would help build resistance to colds and worms in pigs; that it would aid in the prevention of ordinary scours; that it would be efficacious in the treatment of scours in calves; that it would tend to free pigs from worms; and that it would prevent disease in chicks and keep them free from worms and reduce death losses among the chicks were false and misleading since the article would not be efficacious for the purposes recommended.

It was also alleged to be misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods, No. 5688.

On February 6, 1943, the defendants entered a plea of guilty and the court imposed a fine of $100, which was applicable to both defendants.

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PRODUCTS

[1] Prosecution contested.
[2] Prosecution contested. Contains opinion of the court.

SHIPPERS AND MANUFACTURERS

[2] Prosecution contested. Contains opinion of the court.
[3] Contains opinion of the court.
[4] Permanent injunction issued.
[5] Permanent injunction issued. Contains opinion of the court.
[6] Seizure contested. Contains opinion of the court.

[1] Prosecution contested.
[2] Prosecution contested. Contains opinion of the court.
[3] Contains opinion of the court.
[4] Permanent injunction issued.
[5] Permanent injunction issued. Contains opinion of the court.
[6] Seizure contested. Contains opinion of the court.

U. S. GOVERNMENT PRINTING OFFICE: 1945

D. D. N. J., F. D. C. 1051–1100

Issued April 1945

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

1051–1100

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

WATSON B. MILLER, *Acting Administrator, Federal Security Agency.*

WASHINGTON, D. C., *January 24, 1945.*

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DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

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On July 15, 1943, the United States attorney for the Eastern District of Pennsylvania filed an information against the National Drug Co., a corporation, Philadelphia, Pa., alleging shipment from on or about November 11 to December 31, 1942, from the State of Pennsylvania into the States of Kansas, Missouri, Colorado, Georgia, Virginia, and Ohio of quantities of the above-named product, which was misbranded.

Examination of samples disclosed that the article contained pyrogens.

The article was alleged to be misbranded in that, by reason of the presence of pyrogens, it was dangerous to health when used in the dosage prescribed, recommended, and suggested in the labeling, "The contents of a 50 cc. ampul containing the 2½% solution, mixed with 450 cc. of blood produces a transfusion mixture." It was alleged to be misbranded further in that the statement in its labeling, "For use in transfusions to prevent the clotting of blood," was misleading, since the

*For omission of, or unsatisfactory, ingredients statements, see Nos. 1053, 1075, 1087, 1088, 1093, 1097, 1100; failure to bear adequate statements of quantity of contents, Nos. 1055, 1062, 1075, 1099; cosmetic, subject to the drug provisions of the Act, Nos. 1073, 1090.

article would not be safe or appropriate for use in transfusions to prevent the clotting of blood.

On September 22, 1943. the defendant having entered a plea of nolo contendere, the court imposed a fine of $500 on each of 8 counts, a total of $4,000.

1052. Misbranding of Re-Sude-Oids. U. S. v. 20 Packages of Re-Sude-Oids. Default decree of condemnation and destruction. (F. D. C. No. 10033. Sample No. 42658–F.)

On or about June 18, 1943, the United States attorney for the District of Oregon filed a libel against 20 packages of Re-Sude-Oids at Portland, Oreg., alleging that the article had been shipped on or about May 11, 1943, by the American Medicinal Products, Inc., from Los Angeles, Calif.; and charging that it was misbranded.

Examination showed that the article consisted of capsules containing, in each, approximately 0.68 grain thyroid, 0.41 grain potassium iodide, 0.02 grain phenolphthalein and dried glandular tissue.

The article was alleged to be misbranded in that it was dangerous to health when used in the dosage and with the frequency or duration prescribed, recommended, and suggested in the labeling thereof: (On bottle label, carton, and circular enclosed in the package) "Take one capsule daily for six days, then one capsule twice a day for six days, then one capsule three times a day with all following bottles." The article was alleged to be misbranded further in that the statements appearing in its labeling which created the impression in the minds of readers that the article was a safe, appropriate, and effective treatment for obesity were false and misleading, since the article was not a safe, appropriate, or effective treatment for such conditions, but was a potentially harmful drug.

On August 10, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

1053. Misbranding of Chynos. U. S. v. Watchung Laboratories and Emil J. Widmer. Pleas of guilty. Fines, $50 on count 1 and $500 on count 2 as to each defendant. Payment of fines on count 2 suspended and defendants placed on probation. (F. D. C. No. 9642. Sample No. 18924–F.)

On June 3, 1943, the United States attorney for the District of New Jersey filed an information against the Watchung Laboratories, a corporation, Bound Brook, N. J., and Emil J. Widmer, president and treasurer of the corporation, alleging shipment on or about October 26 and December 12, 1942, from the State of New Jersey into the State of New York of quantities of the above-named product.

Analyses of samples of the article showed that it was in the form of tablets which consisted essentially of aminopyrine (approximately 2 grains per tablet) and by hydroxyquinoline sulfonic acid.

The article was alleged to be misbranded in that it was not designated solely by a name recognized in an official compendium; it was fabricated from two or more ingredients, one of which was aminopyrine (amidopyrine); and its label did not bear the common or usual name of each active ingredient, including the quantity or proportion of aminopyrine named therein. It was alleged to be misbranded further in that it contained aminopyrine, which might cause the serious blood disturbance known as agranulocytosis, and might therefore produce serious or fatal injury unless used under adequate and continuous medical supervision; and its label failed to bear such adequate warnings against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users.

On June 21, 1943, the defendants having entered pleas of guilty, the court imposed upon each defendant a fine of $50 on count 1 and a fine of $500 on count 2. Payment of the fines on count 2 were suspended, and the defendants were placed on probation for a period of 1 year.

1054. Adulteration and misbranding of effervescing solution citrated magnesia. U. S. v. Henry Perlmuter (Crystal Drug and Magnesia Co., and White-Stone Laboratories). Plea of guilty. Fine, $50. (F. D. C. No. 9655. Sample No. 19441–F.)

On June 22, 1943, the United States attorney for the District of Massachusetts filed an information against Henry Perlmuter, trading as the Crystal Drug and Magnesia Co. and as the White-Stone Laboratories, Dorchester,

Mass., alleging shipment on or about August 5, 1942, from the State of Massachusetts into the State of Rhode Island of a quantity of the above-named product.

The article was alleged to be adulterated in that it purported to be solution of magnesium citrate, a drug the name of which was recognized in the United States Pharmacopoeia (eleventh revision), an official compendium, but its strength differed from and its quality fell below the standard set forth therein, since the compendium provided that solution of magnesium citrate should contain, in each 100 cc., an amount of magnesium citrate corresponding to not less than 1.6 gram of MgO (magnesium oxide), and should contain citric acid and syrup in the proportion of 33 grams of citric acid and 60 cc. of syrup to each 350 cc., whereas the article contained little if any magnesium citrate, but did contain magnesium sulfate, a substance which is not contained in solution of magnesium citrate compounded in accordance with the standard set forth in the compendium, in an amount corresponding to 1.14 grams of magnesium oxide per 100 cc.; and the article contained citric acid in the proportion of not more than 2 grams per 350 cc., and syrup in the proportion of not more than 29 cc. to each 350 cc.; and its difference in strength, quality, and purity from the standard set forth in the compendium was not stated on its label.

The article was alleged to be misbranded in that its label failed to bear adequate warnings against use in those pathological conditions wherein its use might be dangerous to health, and against unsafe dosage or duration of administration, in such manner and form as are necessary for the protection of users, since the article was a laxative and its labeling failed to bear a warning that it should not be taken when nausea, vomiting, abdominal pains, or other symptoms of appendicitis are present; and that frequent or continued use of the article might result in dependence on laxatives to move the bowles.

On July 6, 1943, the defendant having entered a plea of guilty, the court imposed a fine of $25 on each of 2 counts, a total fine of $50.

1055. Adulteration and misbranding of Cocoa Quinine. U. S. v. 58⅔ Dozen Packages of Cocoa Quinine. Default decree of condemnation. Product ordered delivered to government hospitals. (F. D. C. No. 9609. Sample No. 10264–F.)

Examination showed that this product contained from 8.5 to 9.72 grains of quinine per fluid ounce, and that the bottles contained from 1.79 to 1.86 fluid ounces.

On March 31, 1943, the United States attorney for the Southern District of Alabama filed a libel against 58⅔ dozen packages of Cocoa Quinine at Mobile, Ala., alleging that the article had been shipped on or about November 17, 1942, from Blakeley, Ga., by the South Georgia Manufacturing Co.; and charging that it was adulterated and misbranded. The article was labeled in part: "Home Brand Cocoa Quinine."

The article was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess, namely, "Contains in each fluid ounce Quinine Sulfate 10 Grains."

It was alleged to be misbranded in that the statements appearing in its labeling, "Contains in each fluid ounce Quinine Sulfate 10 Grains * * * Net Contents 2 Ounces," were false and misleading: in that it was in package form and did not bear a label containing an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; and in that its label did not bear adequate directions for its use, since the directions on the label did not specify the dose for children between the ages of 1 and 10.

On July 28, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to government hospitals to be dispensed to the inmates thereof.

1056. Adulteration and misbranding of blue ointment. U. S. v. Herman Achs (Certified Laboratories). Plea of nolo contendere. Fine, $300. (F. D. C. No. 9659. Sample No. 23328–F.)

On July 21, 1943, the United States attorney for the Eastern District of Pennsylvania filed an information against Herman Achs, trading as the Certified Laboratories, Philadelphia, Pa., alleging shipment on or about January 11, 1943, from the State of Pennsylvania into the State of New Jersey of a quantity of blue ointment.

The article was alleged to be adulterated in that it purported to be and was represented as blue ointment, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from and its quality fell below the standard set forth therein, since the com-

pendium provides that blue ointment shall contain not more than 11 percent of Hg (mercury), and shall be so compounded and prepared that the globules of mercury are not visible under a lens mangnifying 10 diameters, whereas the article contained mercury in amounts varying from 28.8 percent to 55.3 percent, and globules of mercury were easily visible in the article under a magnification of 10 diameters; and its difference in strength and quality from the standard set forth in the compendium was not stated on its label.

The article was alleged to be misbranded (1) in that the statement in its labeling, "Blue Ointment (Mild Mercurial, U. S. P.)," was false and misleading; (2) in that its label bore no direction for use; and (3) in that its label failed to bear adequate warnings against use whereby it might be dangerous to health, and against unsafe methods of application, since the article may cause irritation of the skin and its application to large areas may cause serious mercurial poisoning, and the label did not bear warnings in such manner and form as are necessary for the protection of users.

On August 25, 1943, the defendant having entered a plea of nolo contendere, the court imposed a fine of $300.

1057. Misbranding of Korjena. U. S. v. 25 Gross Packages of Korjena (and 26 other seizure actions against Korjena). Decrees of condemnation and destruction. (F. D. C. Nos. 9113, 9276 to 9278, incl., 9331, 9335, 9381, 9402, 9415, 9425, 9516, 9522, 9544, 9555, 9557, 9586, 9597, 9720, 9732 to 9734, incl., 9753, 9754, 9781, 9782, 9812, 9824. Sample Nos. 711–F, 734–F, 1383–F, 1384–F, 3555–F, 3593–F, 6095–F, 7698–F, 8694–F, 13925–F, 14805–F, 16141–F, 20164–F, 20504–F, 21470–F, 21673–F, 23334–F, 28169–F, 31973–F, 32488–F, 32489–F, 37633–F, 44590–F, 44616–F, 44619–F, 44621–F.)

Between January 5 and April 23, 1943, the United States attorneys for the Southern District of California, the Eastern and Western Districts of Missouri, the Eastern and Western Districts of Pennsylvania, the Eastern and Western Districts of Michigan, the Southern District of Florida, the Northern and Southern Districts of Ohio, the Northern District of Illinois, and the Districts of Minnesota, Colorado, Rhode Island, New Jersey, Connecticut, and Massachusetts filed libels against the following quantities of Korjena: 348 dozen packages at Los Angeles, Calif.; 239¼ dozen packages at Kansas City, Mo.; 63½ dozen packages at Philadelphia, Pa.; 11¾ dozen packages at Erie, Pa.; 9½ dozen boxes at Minneapolis, Minn.; 132 dozen packages at Detroit, Mich.; 21⅙ dozen packages at Denver, Colo.: 3⅔ dozen packages at Pawtucket, R. I.; 42 dozen packages at Tampa, Fla.; 26 dozen packages at Jersey City, N. J.; 11⅔ dozen packages at Cincinnati, Ohio; 151¾ dozen packages at Chicago, Ill.; 30⅙ dozen packages at West Haven, Conn.; 473⁷⁄₁₂ dozen packages at Grand Rapids, Mich.; 8 dozen packages at Newark, N. J.; 10¹⁄₁₂ dozen packages at Boston, Mass.; 25¾ dozen packages at Cleveland, Ohio; 14⅙ dozen packages at St. Paul, Minn.; 20¾ dozen packages at Youngstown, Ohio; 40⁵⁄₁₂ dozen packages at St. Louis, Mo.; and 37½ dozen packages at Passaic, N. J. It was alleged that the article had been shipped within the period from on or about August 4, 1942, to March 5, 1943, from Elmira, N. Y., by the Korjena Medicine Co.; and it was charged that it was misbranded.

Examination showed that the article was in the form of tablets which consisted essentially of phenolphthalein (1 grain per tablet), calcium carbonate, material derived from bile, and calcium iodide.

The article was alleged to be misbranded in that the following statements appearing in its labeling, "A Dependable Treatment for the Reduction of Excessive Fat * * * This Treatment is Guaranteed Dependable and may be taken with Complete Confidence * * * Especially in overweight cases of long standing these tablets should be faithfully taken regularly as directed. Two or three packages are usually required for the best results * * * This treatment is dependable in normal conditions. * * * All normal cases of excessive weight may confidently follow above directions. * * *," were false and misleading since the article was not a dependable, safe, and adequate treatment for the reduction of excess fat or weight. It was alleged to be misbranded further in that its label failed to bear adequate directions for use, since the article was a laxative and the directions which appeared in the labeling provided for continuous administration, whereas a laxative should not be used continuously; and in that its labeling failed to warn that the article should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present; that frequent or continued use of the article might result in dependence upon laxatives; and that if a skin rash should appear its use should be discontinued.

Between February 13 and August 9, 1943, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

1058. Misbranding of Davis Formula No. 7895 and standardized solution of vitamin A, and Anti-Ur-Acid and vitamin B_1 tablets. U. S. v. Edward R. Davis (E. R. Davis Prescription Co.). Plea of guilty. Fines, $500 on count 1 and $1 each on counts 2 and 3, plus costs. (F. D. C. No. 7742. Sample Nos. 23097–E, 93233–E, 95346–E.)

On July 30, 1943, the United States attorney for the Western District of Washington filed an information against Edward R. Davis, trading as the E. R. Davis Prescription Co., at Bellingham, Wash., alleging shipment from the State of Washington into the State of California, on or about December 17, 1941, and June 23, 1942, of a number of cartons, each containing a bottle of Davis Formula No. 7895 and a bottle of Standardized Solution of Vitamin A; and into the State of Oregon, on or about May 14, 1942, of a carton containing a box of Anti-Ur-Acid powder and a box of vitamin B_1 tablets.

Analysis showed that the Davis Formula No. 7895 consisted essentially of potassium iodide, an extract of a plant drug such as Lobelia, a small proportion of chloroform, sugar, alcohol, and water; and that the solution of vitamin A contained 32,500 U. S. P. units of vitamin A per gram.

The formula and the solution of vitamin A were alleged to be misbranded in that the statements in their labeling which represented and suggested that, when used as directed, with the diet suggested, they would be an adequate treatment for asthma, including bronchial and spasmodic asthma, were false and misleading since they would not be an adequate treatment for such conditions.

Analysis showed that the Anti-Ur-Acid was a powder consisting essentially of magnesium sulfate, potassium bitartrate, and sodium bicarbonate; and that the vitamin B_1 tablets contained between 0.90 mg. and 0.95 mg. of the vitamin per tablet.

The powder and the vitamin B_1 tablets were alleged to be misbranded in that the name "Anti-Ur-Acid" was misleading, since the name suggested and created the impression in the mind of the reader that the articles would neutralize and correct excess uric acid, whereas they would not neutralize or correct excess uric acid. They were alleged to be misbranded further in that the name "Anti-Ur-Acid," and the statements in the labeling which represented and suggested that rheumatic, neuritic, and arthritic pains, gout, dropsy, and similar disease conditions, suggested by the abbreviation "etc.," were caused by excess uric acid and that the articles would be efficacious in the treatment of those conditions, were false and misleading since those disease conditions are not caused by excess uric acid, and the articles would not be efficacious for the purposes claimed. The articles were alleged to be misbranded further in that the labeling failed to bear adequate directions for use, since the statement "Take about ½ hour before breakfast" created the impression that the powder should be taken every morning, whereas the powder was a laxative and should not be taken continuously.

On November 20, 1943, the defendant having entered a plea of guilty, the court imposed fines of $500 on count 1 and $1 each on counts 2 and 3, plus costs, a total fine of $543.60.

1059. Misbranding of Mrs. Price's Specially Prepared Package of Boric Acid. U. S. v. 53 Packages of Mrs. Price's Specially Prepared Package of Boric Acid (and 5 other seizure actions against the same product). Default decrees of condemnation. Portion of the product ordered delivered to a local public institution; remainder ordered destroyed. (F. D. C. Nos. 9984, 9990 to 9993, incl., 10043. Sample Nos. 22645–F, 22647–F, 22773–F, 22775–F, 23281–F, 23282–F, 23284–F, 32514–F.)

Examination showed that this product consisted of boric acid meeting the requirements of the United States Pharmacopoeia.

Between May 20 and June 7, 1943, the United States attorneys for the Eastern and Middle Districts of Pennsylvania and the Northern District of Ohio filed libels against 53 packages at Wilkes-Barre, Pa., 186 packages at Philadelphia, Pa., 238 packages at Lancaster, Pa., 248 packages at Harrisburg, Pa., 115 packages at Northumberland, Pa., and 5 packages at Cleveland, Ohio, each package containing 12 envelopes of boric acid and 3 pamphlets entitled "Mrs. Price's Complete Directions For Canning Vegetables and Fruits Pickling, etc. * * * ." It was alleged that the article had been shipped within the period from on or about March 15 to April 21, 1943, from Minneapolis, Minn., by the Price Compound Company; and charged that it was misbranded.

The article was alleged to be misbranded (1) in that the statements in its labeling which represented and suggested that boric acid, when used as directed in the canning of vegetables, fruits, and pickles, might safely be used for those purposes, and would effect proper sterilization and destroy bacterial spores capable of causing spoilage, thereby preventing a substantial amount of waste

in home-canned products, were misleading, since such use would be potentially dangerous to the health of the consumer, would not insure proper sterilization, and would not destroy resistant bacterial spores capable of causing spoilage, and thus would not insure the prevention of a substantial amount of waste in home-canned products; (2) in that the statements in its labeling whereby the home canner was admonished to sterilize jars, and particularly rubber rings, by boiling for 15 or 20 minutes were misleading, since the directions for sterilizing were inadequate for the reason that sterilization of jars and rubber rings cannot always be accomplished by boiling for 15 or 20 minutes because of the heat resistance of spore-forming bacteria; (3) in that the statement in its labeling " * * * Wash thoroughly, as the most dangerous and the most difficult bacteria to destroy are in the soil," was misleading since it suggested and represented that the thorough washing of vegetables would eliminate the most dangerous and difficult bacteria to destroy, the common habitat of which is in soil, whereas thorough washing of vegetables will not insure such effects; and (4) in that the statements in its labeling, "Mrs. Price's Specially Prepared Package of Boric Acid Manufactured for, Prepared and Distributed by The Price Compound Company * * * Minneapolis, Minn. * * * It is not claimed that the contents of this package contains anything of food value," were misleading because they failed to reveal the consequences which might result from the use of the article under the conditions prescribed in the labeling, since the processing recommended would not insure proper sterilization and might thereby result in danger to health; and the label further failed to reveal that the amount of boric acid which might be ingested when used as prescribed was such as might render the product deleterious to health. The article was alleged to be misbranded further in that it was a drug and its labeling failed to bear adequate directions for use.

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in the notices of judgment on foods, No. 5760.

Between June 26 and August 9, 1943, no claimant having appeared, judgments of condemnation were entered and it was ordered that the lots at Philadelphia and Lancaster be delivered for the use of some local public institution, and that the other lots be destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

1060. Adulteration and misbranding of ephedrine sulfate. U. S. v. Reuben Seltzer (Success Chemical Co.). Plea of guilty. Fine, $750. (F. D. C. No. 9618. Sample No. 19062-F.)

Analysis of a sample of this product showed that it contained not more than 2.24 grams (2.24 percent) of ephedrine sulfate per 100 cc.

On May 18, 1943, the United States attorney for the Eastern District of New York filed an information against Reuben Seltzer, trading as the Success Chemical Co., Brooklyn, N. Y., alleging shipment on or about July 23, 1942, of a quantity of the above-named article from the State of New York into the State of New Jersey.

The article was alleged to be adulterated in that it purported to be and was represented as a drug, the name of which, "Solution of Ephedrine Sulfate," is recognized in the National Formulary, an official compendium, but its strength differed from and its quality fell below the standard set forth in that compendium since it contained less than 2.8 grams of ephedrine sulphate in each 100 cc., whereas the Formulary provides that "Solution of Ehpedrine Sulfate contains in each 100 cc., not less than 2.8 Gm. * * * of Ephedrine Sulfate"; and its difference in strength and quality from the standard set forth therein was not plainly stated on the label.

It was alleged to be misbranded in that the statement "Ephedrine Sulfate N. F. VI A Solution of 3% Ephedrine Sulfate," borne on its label, was false and misleading.

On June 17, 1943, the defendant having entered a plea of guilty, the court imposed a fine of $250 on count 1, and $500 on count 2, a total of $750.

*See also Nos. 1054–1056.

1061. Adulteration and misbranding of Colloidum Nux Vomica. U. S. v. Lloyd Brothers, Pharmacists, Inc. Plea of guilty. Fine, $400. (F. D. C. No. 9683. Sample Nos. 31961–F, 32012–F.)

On September 8, 1943, the United States attorney for the Southern District of Ohio filed an information against Lloyd Brothers, Pharmacists, Inc., Cincinnati, Ohio, alleging shipment from the State of Ohio into the State of Indiana, on or about October 22 and November 9, 1942, of quantities of the above-named product.

The article was alleged to be adulterated in that its strength differed from that which it was represented to possess, since it was represented to be of the same drug strength as fluidextract of nux vomica, a drug which contains in each 100 cc. not less than 1.05 grams of strychnine; and it was further represented to contain 1.15 percent of strychnine, whereas it contained not more than 0.98 gram of strychnine in each 100 cc., and not more than 0.98 percent of strychnine weight to volume.

The article was alleged to be misbranded in that the statements in its labeling, "Colloidum Nux Vomica * * * Same drug strength as Fluid Extract" and "Standardized to contain 1.15 percent of strychnine," were false and misleading.

On November 2, 1943, the defendant having entered a plea of guilty, the court imposed a fine of $100 on each of 4 counts, a total fine of $400.

1062. Adulteration and misbranding of sodium phosphate. U. S. v. 5 Cases of Sodium Phosphate. Default decree of condemnation and destruction. (F. D. C. No. 9784. Sample No. 7052–F.)

Examination showed that the contents of some packages of this product lost weight, upon drying, in excess of 50 percent (maximum, 58.49 percent), whereas the United States Pharmocopoeia provides that sodium phosphate loses not more than 50 percent in weight upon drying. The product was also short weight.

On April 9, 1943, the United States attorney for the Eastern District of Missouri filed a libel against 5 cases, each containing 144 cans, of sodium phosphate at St. Louis, Mo., alleging that the article had been shipped in interstate commerce by the War Department, from New York, N. Y., on or about March 18, 1943; and charging that it was adulterated and misbranded. The article was labeled in part: "¼ lb. Net Sodium Phosphate U. S. P. * * * Industrial Distributors, Inc New York, N. Y."

The article was alleged to be adulterated in that it purported to be and was represented as a drug, the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from and its quality fell below the standard set forth therein. It was alleged to be misbranded in that it failed to bear a label containing an accurate statement of the quantity of the contents of the package.

On May 27, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1063. Adulteration of sodium citrate. U. S. v. 5,034 Cartons of Sodium Citrate. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 10011. Sample No. 4491–F.)

On or about May 28, 1943, the United States attorney for the Southern District of Ohio filed a libel against 5,034 cartons, each containing 6 ampuls, 50-cc. size, of sodium citrate at Sharonville, Ohio, alleging that the article, which had been consigned on or about April 20, 1943, had been shipped by the Lakeside Laboratories, Inc., from Milwaukee, Wis.; and charging that it was adulterated. The article was labeled in part: "Sterile Sodium Citrate 2.5%."

It was alleged to be adulterated in that it purported to be and was represented as a drug, the name of which, "Anticoagulant Solution of Sodium Citrate No. 3—Sterile Anticoagulant Solution of Sodium Citrate for Parenteral Use," is recognized in the United States Pharmacopoeia, an official compendium, but the quality and purity of the article fell below the pharmacopoeial requirement that it be clear and free from turbidity or undissolved material which can be detected readily when examined in the manner directed by that compendium, since the solution contained undissolved particles which could be detected readily when so examined; and the difference in quality and purity from the official standard was not stated plainly on the label.

On July 14, 1943, the Lakeside Laboratories, Inc., claimant, having admitted the facts set forth in the libel, judgment of condemnation was entered and the product was ordered released under bond for segregation and destruction of all ampuls containing adulterants.

1064. Adulteration of calcium chloride. U. S. v. 200 Cartons of Calcium Chloride (and 7 other seizure actions against calcium chloride). Default decrees of condemnation and destruction. (F. D. C. Nos. 9904, 10069, 10074, 10127, 10323, 11141, 11175, 11280. Sample Nos. 11807–F, 11809–F, 35130–F, 35430–F, 36460–F, 36472–F, 36476–F, 44142–F, 53013–F to 53015–F, incl., 57291–F.)

Samples of the product were found to contain specks, fibers, dust-like particles, and other visible undissolved material, readily discernible by the unaided eye when examined in the manner described in the National Formulary, whereas the Formulary provides that ampuls of calcium chloride shall be substantially free from foreign bodies which can be readily discerned by the unaided eye when examined as provided therein.

Between May 6 and July 27, 1943, the United States attorneys for the Eastern Districts of Missouri and Virginia, the Southern District of Georgia, and the Northern District of California, filed libels against the following amounts of calcium chloride: 200 cartons at St. Louis, Mo.; 600 boxes at Richmond, Va.; 394 boxes at Savannah, Ga.; and 100 cartons at San Francisco, Calif., each carton and box containing 12 ampuls of calcium chloride 10 percent. It was alleged that all shipments of the article with one exception had been shipped by the Pro-Medico Laboratories, Inc., from Brooklyn, N. Y., between the approximate dates of April 7 and 20, 1943; and that one shipment had been made by the Second Zone Transportation Officer from New York, N. Y., on or about April 26, 1943.

On November 19 and 23, 1943, libels were filed in the District of Colorado against 485 cartons, each containing 12 ampuls, of the same product at Denver, Colo., which had been shipped on or about September 25 and October 16, 1943, by the Pro-Medico Laboratories, Inc., from Brooklyn, N. Y.

On December 16, 1943, a libel was filed in the Northern District of New York against 100 cartons, each containing 12 ampuls, of the product at South Schenectady, N. Y., alleging that on or about August 31, 1943, the article had been offered for shipment and introduced into interstate commerce, and shipped from Brooklyn, N. Y., by the Pro-Medico Laboratories, Inc., in pursuance of a contract with the United States War Department, and that it was designed and intended to be delivered and received at various places outside the United States.

The article was alleged to be adulterated in that it purported to be and was represented as a drug, the name of which is recognized in the National Formulary, an official compendium, but its quality and purity fell below the standard set forth therein, and the difference in quality and purity from the standard was not plainly stated on the label.

Between June 15, 1943, and April 15, 1944, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

1065. Adulteration of aromatic ammonia. U. S. v. 747 Cartons of Aromatic Ammonia. Default decree of condemnation and destruction. (F. D. C. No. 10007. Sample Nos. 11799–F, 11805–F.)

On May 26, 1943, the United States attorney for the Northern District of California filed a libel against 747 cartons, each containing 10 ampuls, of aromatic ammonia at San Francisco, Calif., alleging that the article had been shipped on or about December 16, 1942, by the Handy Pad Supply Co., from Worcester, Mass.; and charging that it was adulterated. The article was labeled in part: "Aromatic Ammonia For use as Smelling Salts."

The article was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess, since the specifications under which the article was purchased by the consignee provided in part, "Each ammonia inhalant shall consist of a thin sealed glass ampule * * * having a free ammonia content of not less than 15 percent," whereas the article contained not more than 9.3 percent free ammonia.

On September 15, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1066. Adulteration of sterile phenolsulfonphthalein. U. S. v. 1,136 Cartons, each containing 10 Ampuls, of Sterile Phenolsulfonphthalein. Default decree of condemnation and destruction. (F. D. C. No. 9766. Sample No. 44702–F.)

On April 9, 1943, the United States attorney for the Northern District of Ohio filed a libel against the above-named product at Toledo, Ohio, alleging that the article has been shipped in interstate commerce on or about March 25, 1943, by the Pro-Medico Laboratories, Inc., from Brooklyn, N. Y.; and charging

that it was adulterated. The article was labeled in part: "Sterile 1 cc Phenolsulfonphthalein 6 mgs. (1/10 gr.) Intraven.-Intramusc."

The article was alleged to be adulterated in that it purported to be and was represented as a drug, the name of which, "Phenolsulfonphthalein Injection," is recognized in the United States Pharmacopoeia, an official compendium which requires that injections which are solutions of soluble medicaments must be clear and free of any turbidity or undissolved material which can be detected readily, without magnification, when examined in accordance with the method described therein, but the quality and purity of the article fell below the standard since numerous undissolved particles could be detected readily, without magnification, when so examined.

On June 30, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed. On July 10, 1943, an amended decree was entered ordering that 10 cartons of the product be released to a representative of the Food and Drug Administration, and that the remainder be destroyed.

1067. Adulteration of cotton. U. S. v. 63 Gross Packages of Cotton. Default decree of condemnation. Product ordered delivered to the American Red Cross. (F. D. C. No. 8426. Sample No. 14007-F.)

On September 25, 1942, the United States attorney for the Southern District of California filed a libel against 63 gross packages of cotton at Los Angeles, Calif., alleging that the article had been shipped on or about March 13 and 19, and April 9, 1942, by the Hampton Manufacturing Co., from Carlstadt, N. J.; and charging that it was adulterated. The article was labeled in part: "Blue Cross Cotton * * * Weight not less than 25 grains."

The article was alleged to be adulterated in that it purported to be and was represented as a drug, the name of which is recognized in the United States Pharmacopoeia, but its quality and purity fell below the standard set forth therein, since the article was not sterile but was contaminated with viable gram-positive nonsporulating bacilli.

On November 24, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to a local chapter of the American Red Cross.

1068. Adulteration and misbranding or horsehair ligatures. U. S. v. 126 Jars of Horsehair Ligatures. Default decree of condemnation and destruction. (F. D. C. No. 10081. Sample No. 44159-F.)

On June 11, 1943, the United States attorney for the Eastern District of New York filed a libel against 126 jars, each containing 25 strands, of horsehair ligatures at Brooklyn, N. Y., alleging that the article had been shipped on or about May 13, 1943, by Arthur E. Look, Inc., from Roslindale, Boston, Mass.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its purity and quality fell below that which it purported or was represented to possess, namely, "Sterile."

It was alleged to be misbranded in that the statement "Sterile," appearing upon its label, was false and misleading since the article was not sterile but was contaminated with living micro-organisms.

On August 18, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1069. Adulteration and misbranding of adhesive strips. U. S. v. 114 Dozen Packages of Adhesive Strips. Default decree of condemnation and destruction. (F. D. C. No. 9823. Sample No. 21196-F.)

On April 19, 1943, the United States attorney for the Western District of Pennsylvania filed a libel against 114 dozen packages of adhesive strips at Pittsburgh, Pa., alleging that the article had been shipped by the Hampton Manufacturing Co. on or about March 4, 1943, from Carlstadt, N. J.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that it purported to be a drug, adhesive absorbent gauze, the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its purity fell below the standard set forth therein since the compendium provides that adhesive absorbent gauze must be sterile and meet the requirements of the sterility tests for solids prescribed therein, whereas the article was not sterile but was contaminated wtih living organisms, and its difference in purity from the standard set forth in the Pharmacopoeia was not plainly stated on its label.

It was alleged to be misbranded in that the following statements appearing on its label, "Blue * * * Cross Adhesive Strips * * * For Sports Use For Home Use * * * Thoroughly cleanse wound with a recognized antiseptic. Remove crinoline. Be sure when applying Adhesive Strip that only gauze pad covers the wound," were false and misleading since such statements represented and suggested and created the impression that the article was a safe and appropriate bandage for first aid use on broken skin, whereas it was not a safe and appropriate bandage for such use since it was contaminated with living organisms.

On June 8, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1070. Adulteration and misbranding of first aid dressings. U. S. v. 475,000 Packages of First-Aid Dressings. Consent decree of condemnation. Product ordered released under bond to be destroyed or brought into compliance with the law. (F. D. C. No. 8941. Sample Nos. 3452-F, 3453-F.)

On December 7, 1942, the United States attorney for the District of Kansas filed a libel against 475,000 packages of first-aid dressings at Kansas City, Kans., alleging that the article had been shipped on or about September 18 and 24, 1942, by Convenience, Inc., Greenville, S. C.; and charging that it was adulterated and misbranded. The article was labeled in part: "Small First-Aid Dressing U. S. Army Carlisle Model Sterilized."

The article was alleged to be adulterated in that its purity and quality fell below that which it purported and was represented to possess, namely, "Sterilized."

The article was alleged to be misbranded in that the statements on its label, "Sterilized * * * Red Color Indicates Back of Dressing Put Other Side Next to Wound," were false and misleading since such statements created the impression that the article was sterile, whereas it was not sterile but was contaminated with living micro-organisms.

On December 7, 1942, Convenience, Inc., claimant, having consented to the entry of the decree, judgment of condemnation was entered and the product was ordered released under bond to be destroyed or brought into compliance with the law under the supervision of the Food and Drug Administration.

1071. Adulteration and misbranding of zinc oxide ointment. U. S. v. 354 Jars of Zinc Oxide Ointment. Default decree of condemnation and destruction. (F. D. C. No. 9923. Sample No. 38279-F.)

On May 14, 1943, the United States attorney for the Northern District of Illinois filed a libel against 354 1-pound jars of zinc oxide ointment at Hines, Ill., alleging that the article had been shipped in interstate commerce on February 13, 1943, by Trade Laboratories, Inc., from Newark, N. J.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from the standard set forth therein since the compendium provides that zinc oxide ointment shall contain not less than 18.5 percent and not more than 21.5 percent of zinc oxide, whereas the zinc oxide content of the article was extremely variable, ranging from 12.8 percent to 22.65 percent, and its difference in strength from the standard set forth in the Pharmacopoeia was not plainly stated on its label.

It was alleged to be misbranded in that the designation "Zinc Oxide Ointment U. S. P.," appearing in the labeling, was false and misleading.

On June 11, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1072. Adulteration and misbranding of zinc oxide ointment. U. S. v. 70 Jars of Zinc Oxide Ointment. Default decree of condemnation and destruction. (F. D. C. No. 10023. Sample No. 24694-F.)

Examination showed that this product contained not more than 15.43 percent of zinc oxide.

On May 27, 1943, the United States attorney for the District of Maryland filed a libel against 70 jars of zinc oxide ointment at Perry Point, Md., alleging that the article had been shipped from Long Island City, N. Y., on or about February 8, 1943, by Cole Laboratories, Inc.; and charging that it was adulterated and misbranded. The article was labeled in part: "Retort Pharmaceutical Co. * * * Long Island City, N. Y."

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from the standard set forth therein since the compendium provides that zinc oxide ointment shall contain not less than 18.5 percent of zinc oxide, whereas the article contained less than 18.5 percent of zinc oxide, and its difference in strength from the standard set forth in the Pharmacopoeia was not plainly stated on its label.

It was alleged to be misbranded in that the statement "Unguentum Zinci Oxidi Zinc Oxide Ointment U. S. P.," appearing on the label, was false and misleading since the article did not comply with the United States Pharmacopoeia standards.

On June 28, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1073. Adulteration and misbranding of Azone. U. S. v. 68 Bottles of Azone. Default decree of condemnation and destruction. (F. D. C. No. 9919. Sample No. 32512–F.)

On May 19, 1943, the United States attorney for the Northern District of Ohio filed a libel against 68 bottles of Azone at Cleveland, Ohio, alleging that the article had been shipped on or about February 9 and 22, 1943, by F. G. Schaaf, Minneapolis, Minn.; and charging that it was adulterated and misbranded.

Chemical analysis showed that the article consisted essentially of volatile oils including oil of Cassia and methyl salicylate, tannic acid, glycerol, alcohol 20.0 percent by volume, and water colored with a red dye. Bacteriological examination showed that the article, when diluted 1 part to 3 parts of water, failed to kill *Staphylococcus aureus* in 1 hour.

The article was alleged to be adulterated in that its strength differed from that which it purported or was represented to possess, (label) "Owing to its * * * antiseptic properties," and "DIRECTIONS MOUTH WASH—Any desired dilution may be used as often as desired."

The article was alleged to be misbranded in that the statements quoted above, which appeared in its labeling, were false and misleading as applied to an article that was not antiseptic in "Any desired solution"; and in that the statement in its labeling, "Alcohol 14.54%," was false and misleading since it was incorrect.

On August 9, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1074. Adulteration and misbranding of mild tincture of iodine. U. S. v. 45 Dozen Bottles of Mild Tincture of Iodine. Default decree of condemnation and destruction. (F. D. C. No. 9916. Sample No. 41326–F.)

Examination showed that this product contained in each 100 cc. not more than 1.46 grams of iodine, whereas the United States Pharmacopoeia (eleventh and twelfth revisions) provides that "Mild Tincture of Iodine contains, in each 100 cc. not less than 1.8 Gm. and not more than 2.2 Gm. of I."

On May 13, 1943, the United States attorney for the Southern District of Mississippi filed a libel against 45 dozen bottles of mild tincture of iodine at Jackson, Miss., alleging that the article had been shipped from on or about October 28, 1942, to January 7, 1943, from Memphis, Tenn., by McKesson and Robbins—Van Vleet Division; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that it was represented as a drug the name of which is recognized in an official compendium; but its strength differed from the standard set forth in the compendium, and that difference was not stated on the label.

The article was alleged to be misbranded in that the statement "Mild Tincture of Iodine U. S. P.," appearing on its label, was false and misleading since the article did not comply with the United States Pharmacopoeia standard.

On November 4, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1075. Adulteration and misbranding of Orbolene. U. S. v. 122 Packages of Orbolene. Default decree of condemnation and destruction. (F. D. C. No. 9852. Sample No. 24783–F.)

On April 28, 1943, the United States attorney for the Eastern District of North Carolina filed a libel against 122 packages of Orbolene at Wilmington, N. C., alleging that the article had been shipped on or about February 26, 1943, by the Orbolene Co., St. Louis, Mo.; and charging that it was adulterated and misbranded.

Examination showed that the article consisted essentially of water, boric acid, glycerin, carbolic acid, ephedrine, and a red coloring material. Bacteriological tests showed that the article was not antiseptic.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess, i. e., antiseptic.

The article was alleged to be misbranded because of false and misleading statements in its labeling: (Vial carton label) "Orbolene promotes a * * * healthy condition of the eyes and is used * * * in the treatment of weak, inflamed, sticky, sore, irritated eyes and eyelids: acute and chronic catarrhal conjunctivitis, or congestion of the eye caused by colds, overwork or exposure to sun, wind, dust, etc. * * * antiseptic"; (circular) "Weak, tired and painful vision caused by dust, wind, strong light and close application to near work. * * * If * * * inflamed use Orbolene * * * Eye Troubles Close application to near work is the cause of much eye trouble. Mechanics and workers in offices and factories where the lighting system is poor frequently find that at the close of the day their eyes burn and sting. This condition can be helped by the use of Orbolene twice daily. * * * It is soothing and restful to eyes affected by Hay Fever and Rose Cold." The article was not effective in the treatment of the conditions stated and implied. It was alleged to be misbranded further (1) in that it was in package form and its label failed to bear an accurate statement of the quantity of its contents, since no statement of the quantity of contents appeared on the label of the vial, and the statement appearing on the carton, "Contents 7 c. c.," was incorrect; and (2) in that it was fabricated from two or more ingredients and its label failed to bear the common or usual name of the active ingredients contained therein, since no statement of the active ingredients appeared on the carton, and phenol and hydrogen borate were not given their common or usual names of carbolic acid and boric acid, respectively, in the statement of active ingredients which appeared on the vial label.

On June 18, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1076. Adulteration and misbranding of prophylactics. U. S. v. 63 Gross of Rubber Prophylactics. Default decree of condemnation and destruction. (F. D. C. No. 10109. Sample No. 47389–F.)

On June 18, 1943, the United States attorney for the Western District of Tennessee filed a libel against 63 gross of rubber prophylactics at Memphis, Tenn., alleging that the article had been shipped on or about April 19, 1943, by Hardy Newman & Co., from Chicago, Ill.; and charging that it was adulterated and misbranded. The article was labeled in part: (Individual packages) "One Quarter Dozen '400' Latex Product * * * Rubber Prophylactic Devices."

Examination of 100 samples of the article showed that 15 percent were defective in that they contained holes.

The article was alleged to be adulterated in that its quality fell below that which it purported to possess.

It was alleged to be misbranded in that the statement "Prophylactic Devices," appearing on the label, was false and misleading as applied to the article.

On August 25, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

DRUGS FOR HUMAN USE**

1077. Misbranding of wheat germ. U. S. v. Commander Larrabee Milling Co. (Minneapolis Milling Co.). Plea of guilty. Fine, $100. (F. D. C. No. 9677. Sample No. 37818–F.)

On October 21, 1943, the United States attorney for the District of Minnesota filed an information against the Commander Larrabee Milling Co., trading as the Minneapolis Milling Co., Minneapolis, Minn., alleging shipment on or about January 21, 1943, from the State of Minnesota into the State of Illinois of a quantity of wheat germ which was misbranded. The article was labeled in part: "P. W. G. (Pure Wheat Germ)."

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* See also Nos. 1051, 1052, 1055–1061, 1068–1076.
**See also No. 1093.

The article was alleged to be misbranded because of false and misleading statements in the labeling which represented and suggested that it would be an effective treatment for pellagra and beriberi; that it would be effective as a preventative of mental diseases; that it would be an effective treatment and preventative of skin eruptions, brown scaly patches in localized areas, indigestion, and disturbances of the nervous system; that it would prevent sterility and promote the maturing of the normal germ cell in the male and the natural placental functioning in the female; that it would promote health, vigor, strength, and energy, and would benefit man, woman, or child who was undernourished or who required a general toning up; that it would improve the appetite, aid growth, and induce the normal functioning of the nervous system and intestinal tract; and that it would insure normal reproduction and lactation in mothers. The article would not be effective for such purposes.

It was alleged to be misbranded further in that the statements in the labeling which represented and suggested and created the impression that the disease conditions and functional impairment for which the product was recommended as stated above are usually the result of lack of vitamin B_1, riboflavin, and nicotinic acid, and that the reader might reasonably expect correction and alleviation of such conditions by the use of the article, were misleading since such conditions are not usually the result of lack of the vitamins named, but usually result from other causes, and the reader might not reasonably expect their correction and alleviation since the article would not ordinarily be effective for such purposes.

The article was also alleged to be misbranded under the provisions of the law applicable to food, as reported in notices of judgment on food, No. 5784.

On October 21, 1943, a plea of guilty was entered to all charges and the court imposed a fine of $100, which covered both counts of the information.

1078. Misbranding of Vigor 8. U. S. v. 60 Cases of Vigor 8 and 2,000 Leaflets. Default decree of condemnation and destruction. (F. D. C. No. 9806. Sample No. 37662–F.)

On April 19, 1943, the United States attorney for the Eastern District of Michigan filed a libel against 60 cases, each containing 12 10-ounce jars of Vigor 8, and 2,000 leaflets entitled "Charles D. Kasher's Health and Beauty Chart," at Detroit, Mich., alleging that the article and the leaflets had been shipped on or about March 23, 1944, by the Royal Products Co., Chicago, Ill.; and charging that the article was misbranded.

Examination disclosed that the article contained dried brewers' yeast, corn flour, corn germ, and wheat germ.

It was alleged to be misbranded in that the statements, designs, and devices on the labels attached to the jars and in the above-mentioned leaflets were false and misleading since they represented and suggested that the article was of significant nutritional value by reason of the presence of vitamin B_6, vitamin E, and other factors of the B complex as found in brewers' yeast, and the elements potassium, sulfur, sodium, magnesium, copper, zinc, chlorine, and manganese; and that consumption of the product would insure normal functioning of the various organs of the body, and would prevent and correct abnormalities of those organs and such disease conditions as cold infection, ulceration, stone formation, cystitis, spasms, cramps, exhaustion, inflammation, paralysis, conjunctivitis, cataract, night blindness, scaliness, dryness and paleness of the skin, skin sores, gum infections, scurvy, loose teeth, and diabetes, whereas the article was not of significant nutritional value by reason of the presence of the vitamins, factors, and elements mentioned, and consumption of the article would not insure normal functioning of the various organs of the body and would not prevent or correct abnormalities of those organs, or the disease conditions mentioned and suggested.

The article was also alleged to be misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods.

On July 16, 1943, no claimant having appeared, judgment of condemnation was entered and the product and the leaflets were ordered destroyed.

1079. Misbranding of Cellasin No. 1 Tablets. U. S. v. 22 Bottles of Cellasin No. 1 Tablets. Consent decree of condemnation and destruction. (F. D. C. No. 8891. Sample No. 21747–F.)

On November 19, 1942, the United States attorney for the Western District of Pennsylvania filed a libel against 22 bottles, each containing 200 tablets, of Cellasin No. 1 at Pittsburgh, Pa., alleging that the article had been shipped by the American Ferment Co., from Buffalo, N. Y., on or about October 20, 1942; and charging that it was misbranded. The article was labeled in part: "Active

Ingredients Vitamin B_1 Vitamin B_2 From Dried Whole Yeast Powder Desiccated Whole Pancreas Substance Sodium Bicarbonate."

Examination of the article showed the presence of sodium bicarbonate, dried yeast, and unidentified animal tissues. These findings indicated that the product was essentially of the composition declared on its label. Additional examination of the article showed that it contained the declared vitamin content.

The article was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that, when taken as directed, it would be of value in the treatment of faulty carbohydrate metabolism, anorexia, obesity, polyneuritis, and diabetes (a particular form of faulty carbohydrate metabolism); and that the use of the article would result in improved intellectual and physical vigor, increased body weight, and good health, were false and misleading since the article, when taken as directed, would not be of such value, and its use would not accomplish the results suggested and implied.

On November 22, 1943, the American Ferment Co. having filed a claim and answer denying the allegation of misbranding, but later having withdrawn the claim and answer and consented to the entry of a decree, judgment of condemnation was entered and the product was ordered destroyed.

1080. Misbranding of Vitality Vitamins. U. S. v. 41 Cartons of Vitality Vitamins. Default decree of condemnation and destruction. (F. D. C. No. 9408. Sample No. 13263–F.)

On March 13, 1943, the United States attorney for Western District of Washington filed a libel against 41 cartons, each containing 20 boxes of 7 capsules each, of Vitality Vitamins at Seattle, Wash., alleging that the article had been shipped on or about December 31, 1942, from Chicago, Ill., by the Belmont Laboratories; and charging that it was misbranded. The article was labeled in part: "Vitality Vitamins Contain Vitamins A . B_1 . D . G(B_2)."

The article was alleged to be misbranded in that certain statements on the cartons and individual boxes and in a circular entitled "Know Your Vitamins," inserted in each carton, were false and misleading since they represented and suggested that the article was efficacious in the correction or prevention of lowered resistance, coughs, colds, retarded growth, loss of weight, eye diseases, intestinal disorders, nervousness, constipation, slow heart rate, loss of appetite, reduced well-being, dental decay, poor tooth development, rickets, and soft bones, whereas the article was not so efficacious; and the said statements compared the vitamin content of the article with that of eggs, milk, and bananas; and, when read in connection with the statements in the labeling with respect to the loss of vitamins from ordinary foods in the usual manner of preparation, they created the impression that it is not practicable to obtain an adequate amount of vitamins through the consumption of ordinary food as usually prepared, whereas adequate amounts of vitamins can be obtained through the consumption of ordinary food as usually prepared.

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in the notices of judgment on foods.

On September 16, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1081. Misbranding of Allen's Nijara Capsules. U. S. v. 16 Dozen Packages and 71 Boxes of Allen's Nijara Capsules. Decrees of condemnation and destruction. (F. D. C. Nos. 9707, 9739. Sample Nos. 37143–F, 37149–F.)

This product consisted of dried green stem and leaf material, including in one lot such material as parsley and watercress, and in the other a considerable proportion of tissues resembling parsley. Examination of a sample showed that it contained not more than 5 U. S. P. units of thiamine (about $\frac{1}{60}$ the minimum daily requirement of thiamine), and but an inconsequential amount, if any, or ascorbic acid, riboflavin, nicotinic acid, and vitamin D.

On March 25 and April 2, 1943, the United States attorney for the District of Columbia filed libels against 16 dozen packages and 71 boxes of Allen's Nijara Capsules at Washington, D. C., alleging that the article, which had been consigned by the Allen Products Co., Inc., Washington, D. C., on or about February 24 and March 23, 1943, was in interstate commerce; and charging that it was misbranded. It was labeled in part: (Packages and boxes) "Twenty (20) Capsules Allen's Nijara Composed of the following ingredients only: Asparagus, Parsley, Watercress, Broccoli. For Adults: Suggested Daily Dosage: Five (5) capsules daily."

The article was alleged to be misbranded in that the statements in the leaflet entitled "Allen's Nijara," attached to the packages and boxes containing the article, were false and misleading because they represented and suggested that the article was effective to soothe pain, provide relief from rheumatism, arthritis, neuritis, sciatica, gout, lumbago, and sinusitis; that it would supply a mineral deficiency in the diet and provide pain relief from rheumatic disorders; that the article was effective more quickly in the treatment of mild cases of the symtoms and the diseases mentioned than in cases of long standing; and that, when taken in accordance with the directions, it would supply the body with its needs for such important minerals as calcium and phosphorus, and with such important vitamins as thiamine, riboflavin, ascorbic acid, nicotinic acid, and vitamin D. The article was not so effective and would not supply the body with its needs for the minerals and vitamins mentioned.

It was alleged to be misbranded further in that the statement "only fresh vegetables are used in compounding Allen's Nijara," appearing in its labeling, was false and misleading since the article was compounded of dried vegetables, not fresh vegetables, and did not provide the vitamins that some vegetables provide in their fresh state.

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 5795.

On May 12, 1943, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

1082. Misbranding of Wiel Garlic Tablets. U. S. v. 6 Dozen Tins and 69 Bottles of Wiel Garlic Tablets. Default decree of condemnation and destruction. (F. D. C. No. 9903. Sample No. 42111–F.)

On May 8, 1943, the United States attorney for the Northern District of Ohio filed a libel against 6 dozen tins, containing 24 tablets each, and 69 bottles, containing 120 tablets each, of Wiel Garlic Tablets at Toledo, Ohio, alleging that the article had been shipped in interstate commerce on or about January 23, 1943, by the Wiel Laboratories, from Medford Station, Long Island, N. Y.; and charging that it was misbranded.

Examination showed that the article consisted essentially of tablets containing garlic, peppermint, sugar, starch, and calcium carbonate.

The article was alleged to be misbranded in that the statements in its labeling which represented and suggested that the article would effect better health, stimulate digestion, and reduce high blood pressure when taken continuously at prescribed intervals were false and misleading since the article would not accomplish the results claimed.

On June 22, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1083. Misbranding of okra tablets and spinach tablets. U. S. v. Harry Clayton House (Western Natural Foods Co.). Plea of guilty. Fine, $150 and costs. (F. D. C. No. 9653. Sample Nos. 30612–F, 30613–F.)

On July 30, 1943, the United States attorney for the Western District of Washington filed an information against Harry Clayton House, trading as the Western Natural Foods Co., Seattle, Wash., alleging shipment on or about September 3 and October 17, 1942, from the State of Washington into the State of Idaho of quantities of the above-named products.

Analysis of the okra tablets showed that they consisted of dried or powdered okra. The article was alleged to be misbranded because of false and misleading statements in the labeling which represented and suggested that it would be efficacious in the treatment of stomach and intestinal ulcers, and would provide a mucinous coating for the protection of irritated mucous membranes of the stomach and intestines.

Analysis of the spinach tablets showed that they consisted essentially of dried or powdered spinach. The article was alleged to be misbranded because of false and misleading statements in its labeling which represented and suggested that the article would be efficacious in the cure, mitigation, treatment, or prevention of blood disorders and anemia.

The spinach tablets were also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

On August 30, 1943, the defendant having entered a plea of guilty, the court imposed a fine of $100 on count 1 and $50 and costs on count 2.

1084. Misbranding of Leonardi's Elixir. U. S. v. 66 Packages of Leonardi's Elixir. Default decree of condemnation and destruction. (F. D. C. No. 9943. Sample No. 28187–F.)

On May 18, 1943, the United States attorney for the Southern District of Florida filed a libel against 66 packages of Leonardi's Elixir at Tampa, Fla., alleging that the article had been shipped from New Rochelle, N. Y., by S. B. Leonardi and Co., Inc., on or about April 9, 1943; and charging that it was misbranded.

Examination showed that the article consisted essentially of water, potassium iodide, tincture of ferric citrochloride, and extracts from plant drugs.

The article was alleged to be misbranded in that the following statements, which appeared on the cartons in the English language, and similar statements in foreign languages, "Chronic Rheumatism, Gout * * * conditions resulting from exposure or exhausting labor, * * * increases the red corpuscles * * * in the blood," were false and misleading since the article would not be effective for the purposes claimed.

On June 18, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1085. Misbranding of Prostacones. U. S. v. 2⅔ Dozen Boxes of Prostacones. Default decree of condemnation and destruction. Decree amended to provide for delivery of the product to a county agency or charitable institution. (F. D. C. No. 9982. Sample No. 22770–F.)

On May 19, 1943, the United States attorney for the Eastern District of Pennsylvania filed a libel against 2⅔ dozen boxes, each containing 12 Prostacones, at Philadelphia, Pa., alleging that the article had been shipped on or about April 10, 1943, by the Physicians Drug Co., from New York, N. Y.; and charging that it was misbranded.

Examination showed that this article consisted essentially of methenamine, sodium salicylate, theophyllin, and alkaloid-containing material, together with cocoa butter.

The article was alleged to be misbranded in that the statements in its labeling which represented and suggested that, when used as directed, it would be effective for palliation of prostatic distress; that it would soothe the prostatic inflammation; that it would relax spasm of the vesical sphincter; that it would stimulate diuresis and micturition; that it would reduce urgency, dribbling, and burning; that it would avoid infection in catheter cases; and that it would check the progress of enlargement, were false since the article would not be efficacious for those purposes or accomplish the results claimed.

On June 12, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed. On June 23, 1943, an amended decree was entered providing for the delivery of the product to the Delaware County Board of Prison Inspectors, Media, Pa., or to some hospital clinic or charitable institution familiar with the use of the Prostacones.

1086. Misbranding of Kovac Type Culture Lactobacillus Acidophilus. U. S. v. 72 Bottles of Kovac Type Culture Lactobacillus Acidophilus. Default decree of condemnation and destruction. (F. D. C. No. 9126. Sample No. 30806–F.)

On January 7, 1943, the United States attorney for the Western District of Washington filed a libel against 72 bottles of the above-named product at Seattle, Wash., alleging that the article had been shipped from Los Angeles, Calif., by the Kovac Laboratories, within the period from on or about October 17 to December 3, 1942; and charging that it was misbranded.

Examination showed that the article was a broth culture containing from 4,000,000 to 8,000,000 lactobacilli per milliliter.

The article was alleged to be misbranded because of false and misleading statements which appeared in portions of its labeling enclosed in one of the shipments, i. e., in the leaflets entitled "Anti-Toxic Regime," and "Our Body Protectors," and which represented that the article was efficacious in the cure, mitigation, treatment, or prevention of auto-intoxication, toxemia, colitis, ulceration, diabetes, irritated bowels, poison-producing and disease-breeding (pathogenic) organisms generated in the intestinal tract, muddy complexion, offensive sweat, irritability, eruptions, sores, boils, pimples, carbuncles, itching with or without scales, eczema, inflammation of the skin with or without scales, chronic congestion (acne), dizziness (vertigo), stinging, violent, or constant headache, migraine, feeling of discomfort (malaise), depressed mind, physical debility, drowsiness, defective

memory, disturbed sleep, insomnia, fatigue (chronic), nervous irritation, mental stupor, difficult concentration, neuralgia and neuritis, constant backache, general weakness, weakened abdominal muscles leading to obstinate constipation, arthritis, muscular rheumatism and gout, chronic bleeding gums, foul taste, fetid, enlarged tonsils, inflammation of the tonsils, fetid breath (halitosis), white ulcers in the mouth (thrush), fetid nasal discharge, loss of hair, quinsy, asthma, bronchial asthma, bronchitis, hardening of the lungs, dullness or heaviness of the eyes, discharge of pus from the eyes, affected vision, sac under the eye, brown rings under the eyes, hardening of the crystalline lens, soreness, cataract, high blood pressure, low blood presure, enlargement (dilation) of the blood vessels, hardening (induration) of the arteries or arteriosclerosis, varicose veins, toxic blood (uremia), bacterial infection (septicemia), anemias, including chlorosis, degeneration (fatty) of the heart, fainting spells, inflammation of the heart tissues, biliousness, hardening of the liver, torpid liver, abscess of the liver, degeneration of the liver, enlargement of the spleen, jaundice, inflammation of the gall bladder, gall stones, tenderness of the abdomen, distension of the abdomen, abdominal pains, dyspepsia, inflammation of the stomach (gastritis), cancer of the stomach, inflammation of the intestines (enteritis), acute or chronic diarrhea, dysentery, kinks in the colon, catarrh of the intestine, constipation, tuberculosis of the bowels, acidosis, catarrh, strong body odor, rheumatism, depleted body resistance, chronic ulcers, chronic digestive disturbances, systemic toxemia, and premature aging.

On September 16, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1087. Misbranding of Chek-A-Cold. U. S. v. 138 Bottles of Chek-A-Cold. Default decree of condemnation and destruction. (F. D. C. No. 9901. Sample No. 23247–F.)

On or about May 13, 1943, the United States attorney for the District of New Jersey filed a libel against 138 bottles of Chek-A-Cold at Merchantville, N. J., alleging that the article had been shipped on or about February 19, 1943, from Philadelphia, Pa., by the Hance Brothers and White Co.; and charging that it was misbranded. The article was labeled in part: "Each Fluid Ounce Contains: Chloroform . . . 4 minims Alcohol by vol . . . 2 percent Alkaloids of Hyoscyamus .0003 gr. Contains Extract of Cod Liver Oil (Vitamins A and D), Ipecac, Hyoscyamus, Horehound, Wild Cherry, Tar, Spikenard, Tolu, Menthol, Lobelia, White Pine and Tartar Emetic."

Examination showed that the article contained, among other ingredients, 1.17 minims of chloroform per fluid ounce, a small proportion of alcohol, and tartar emetic, and that Hyoscyamus alkaloids, if present at all, were in a proportion too small to permit detection.

The article was alleged to be misbranded in that the designations "Chek-A-Cold," on the carton, and "Chek-A-Col," on the bottle label, were false and misleading since the article would not be effective in checking colds; and in that its label failed to bear the quantity or proportion of chloroform contained in it, since the statement on the label, "Each Fluid Ounce Contains: Chloroform . . . 4 minims," was not a correct statement of the chloroform actually contained in the article.

On July 10, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1088. Misbranding of Pinee Preparation for Colds. U. S. v. 12 Dozen Bottles of "Pinee Preparation Colds." Decree of condemnation and destruction. (F. D. C. No. 9899. Sample No. 25000–F.)

Six samples of this product were examined and were found to contain the following quantities of acetanilid: 2.88, 3.40, 4.83, 3.29, and 3.69 grains per fluid ounce. The product was also found to contain aromatic spirits of ammonia, an alkaloid-bearing drug such as belladonna, cascara sagrada, menthol, and camphor.

On or about May 10, 1943, the United States attorney for the Eastern District of Virginia filed a libel against 12 dozen bottles of the above-named product at Portsmouth, Va., alleging that the article had been shipped on or about November 20, 1942, from Kinston, N. C., by the Pinee Chemical Co.; and charging that it was misbranded.

It was alleged to be misbranded in that the statement "Colds," appearing on its label, was false and misleading since the article would not be effective in the

treatment of colds; and in that the label did not bear a statement of the quantity or proportion of acetanilid present since the statement "* * * in each fluid ounce: acetanilid 3 grs" was incorrect.

On June 30, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1089. Misbranding of Py-Ro. U. S. v. 6⅓ Dozen Bottles and 7⅔ Dozen Bottles of Py-Ro. Default decree of destruction. (F. D. C. No. 10014. Sample No. 3374–F.)

On or about June 21, 1943, the United States attorney for the Western District of Missouri filed a libel against 6⅓ dozen bottles, containing 4 fluid ounces each, and 7⅔ dozen bottles, containing 8 fluid ounces each, of Py-Ro, at Kansas City, Mo., alleging that the article had been shipped on or about April 3, 1943, from New York, N. Y., by Oran Products; and charging that it was misbranded.

Examination showed that the article consisted essentially of sodium hypochlorite, chlorthymol, and oil of peppermint dissolved in water.

The article was alleged to be misbranded in that the name, "Py-Ro," and the statements on the label, "Py-Ro * * * Using cotton saturated with Py-Ro, rub your gums * * * place on each side of affected parts of gums * * * If your gums are too tender due to inflammation * * * Swirl Py-Ro from one side of mouth to the other to force it down into gums and between the teeth * * * As inflammation decreases diminish water until full strength can be used. (This method tends to allay the inflammation of the gums which is usual at beginning of treatment)," were false and misleading, since the name and statements represented and suggested that the article was an effective treatment for pyorrhea, whereas it was not so effective; and in that the statement, "for Trench Mouth Symptoms," appearing on the label, was false and misleading since the article was not an effective treatment for trench mouth.

On August 4, 1943, no claimant having appeared, judgment was entered ordering the destruction of the product.

1090. Misbranding of U–X Improved Shaving Medium. U. S. v. 45⅔ Dozen Packages of U-X Improved Shaving Medium. Tried to the court. Decree of condemnation and destruction. (F. D. C. No. 4098. Sample No. 19198–E.)

On April 1, 1941, the United States attorney for the Western District of Pennsylvania filed a libel against 45⅔ dozen packages of the above-named product at Pittsburgh, Pa., alleging that the article had been shipped on or about October 4 and 21, 1940, by the U-X Manufacturing Co., Inc., from New York, N. Y.; and charging that it was misbranded under the provisions of the law applicable to cosmetics, as reported in the notices of judgment on cosmetics, No. 104.

On May 2, 1941, the U-X Manufacturing Co., Inc., claimant, filed an answer denying that the article was a cosmetic and was misbranded, and on June 7, 1941, pursuant to the stipulation of the parties, the case was ordered removed to the United States District Court for the District of Connecticut. On or about December 10, 1941, the United States attorney for the District of Connecticut filed an amendment to the libel, charging that the article was also misbranded under the provisions of the law applicable to drugs.

Examination showed that the article consisted essentially of magnesium carbonate, peroxide, such as magnesium peroxide and urea peroxide, together with small amounts of soap, gum arabic, and milk sugar.

It was alleged to be misbranded as a drug in that the following statements, appearing on the carton and in a circular contained in the package, were false and misleading since they represented that the article was efficacious for the purposes recommended, whereas it was not efficacious for such purposes: "U–X is absolutely non-irritating. Highly recommended by the medical profession for its skin protecting soothing properties. * * * Redness, smarting and chinchafe will disappear with use of U–X. * * * allowing time for the skin to rid itself of all other substances with which it may have become impregnated by ordinary shaving methods. * * * 'My skin was scraped and chafed. Since using U–X my skin is healthy and clear.' * * * 'My skin is allergic to a pimple condition and U–X is most beneficial.' "

An answer denying the allegations set forth in the amendment to the libel was subsequently filed by the claimant, together with a motion and petition dated February 13, 1942, for the removal of the case to the Southern District of New York. The motion was consented to by the Government's attorney and, on February 16, 1942, an order was entered for the removal of the case to the United States district court for that district. On February 23, 1942, a motion to revoke

the transfer was filed in the aforesaid court for the District of Connecticut and thereafter the court denied the motion, stating that, since the case had been removed and all papers transferred to the Southern District of New York, a proper motion should be addressed to the court for that district. A motion was then filed in the United States district court for the Southern District of New York for the retransfer of the case to the District of Connecticut, and at the conclusion of the argument thereon, which took place on May 8, 1942, the court handed down the following opinion in denial of the motion:

GODDARD, *District Judge:* "The United States Attorney for the Southern District of New York moves for an order transferring this proceeding back to the United States District Court of Connecticut. It is urged in support of this motion that the case had been transferred from the United States District Court for the Western District of Pennsylvania to the United States District Court of Connecticut, and that under the provisions of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. A. § 334 (a)) the Connecticut Court was without power to transfer the case a second time, or to transfer the case to a district where the claimant has his principal place of business.

"Claimant contends that the order transferring the case to this court had been consented to by the United States Attorney for the District of Connecticut, and, accordingly, such transfer was permissible under the statute. I agree with this contention. The statute specifically provides that a proceeding 'pending or instituted' shall on application of the claimant be removed to any district agreed upon by stipulation between the parties. The consent of the United States Attorney for the District of Connecticut was in effect a stipulation. Nowhere is it provided that by stipulation a proceeding may be transferred only once, and then only to a district where the claimant does not have his principal place of business.

"Motion denied. Settle order on notice."

The case came on for trial before the court on October 29 and 30, 1942. At the conclusion of the trial the court took the case under advisement and on November 19, 1942, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS FOR VETERINARY USE

1091. Misbranding of Phen-O-Sal Tablets. U. S. v. Dr. Salsbury's Laboratories. Plea of nolo contendere. Fine, $300 and costs. (F. D. C. No. 7709. Sample Nos. 76746–E to 76748–E, incl.)

On November 23, 1943, the United States attorney for the Northern District of Iowa filed an information against Dr. Salsbury's Laboratories, a corporation, Charles City, Iowa, alleging shipment on or about March 30, 1942, from the State of Iowa into the State of Minnesota of quantities of the above-named product.

Analysis of samples of the article disclosed that the tablets contained sodium phenolsulfonate, calcium phenolsulfonate, zinc phenolsulfonate, boric acid, a sugar, and approximately 0.34 grain of copper arsenite per tablet.

The article was alleged to be misbranded in that the statements in a circular accompanying the article which represented and suggested that it would be efficacious in the cure, mitigation, treatment, or prevention of intestinal diseases, such as diarrhea, fowl cholera, typhoid, coccidiosis, and enteritis, and respiratory diseases, such as pneumonia, bronchitis, mycosis, roup, and colds; and that it would be efficacious in keeping chickens healthy, were false and misleading since it would not be efficacious for those purposes.

On November 23, 1943, the defendant having entered a plea of nolo contendere, the court imposed a fine of $300 and costs.

1092. Misbranding of Dr. Salsbury's Rakos, Can-Pho-Sal, and Phen-O-Sal Tablets. U. S. v. 2 Jugs, 1 Bottle, and 6 Bottles of Rakos (and 2 other seizure actions against the other above-named products). Motion to dismiss filed by the claimant, denied by the court. Tried to a jury; verdict for the Government. Decrees of condemnation and destruction entered. Execution of judgment stayed and motion for new trial filed; motion denied and products ordered destroyed. (F. D. C. Nos. 7564 to 7566, incl. Sample Nos. 76921–E to 76923–E, incl., 76955–E to 76957–E, incl.)

On June 1, 1942, the United States attorney for the District of Minnesota filed libels against the following products at Worthington, Minn.: 2 1-gallon jugs, 1 1-quart bottle, and 6 1-pint bottles of Rakos; 42 1-pint and 38 ½-pint bottles of Can-Pho-Sal; and 123 cans, of various sizes, of Phen-O-Sal Tablets. Thereafter, amended libels were filed to cover additional quantities of the above-named products and to clarify the allegations and, on or about May 28, 1943, further amended

libels were filed to include more specific allegations concerning the accompaniment in interstate commerce of the products by certain printed matter.

It was alleged in the libels as amended that the articles had been shipped in interstate commerce, from Charles City, Iowa, by Dr. Salsbury's Laboratories, within the period from on or about January 16 to May 26, 1942, and that they were misbranded.

Examination of the Rakos showed that it consisted essentially of sulfuric acid, hydrochloric acid, tannic acid, and sugar and water. It was alleged to be misbranded in that certain statements in the booklets entitled "Dr. Salsbury's Poultry Health Messenger," "Step-Up Profits By Improving Turkey Health," "Better Care Brings Greater Profits Now," and "Broiler Health and Disease Manual," were false and misleading, since they represented and suggested that the article was effective in the treatment of blackhead and coccidiosis in poultry, whereas it was not so effective.

Examination of the Can-Pho-Sal showed that it consisted essentially of creosote, camphor, pine oil, eucalyptus oil, soap, and water, with a small proportion of a potassium compound. It was alleged to be misbranded in that certain statements in the booklets were false and misleading since they represented and suggested that the article was effective in the treatment of pneumonia, bowel trouble, bronchitis, colds, and respiratory infections of poultry and farm animals, whereas it was not so effective.

Examination of the Phen-O-Sal Tablets showed that it consisted essentially of sodium phenolsulfonate, 76 percent; calcium phenolsulfonate, 3 percent; zinc phenolsulfonate, 4 percent; copper arsenite, 2.6 percent; boric acid, 12.4 percent; and a sugar. It was alleged to be misbranded in that certain statements in the booklets and in a leaflet entitled "Dr. Salsbury's Phen-O-Sal Tablets", accompanying the article, were false and misleading, since they represented and suggested that the article was effective in the treatment of bowel trouble, paratyphoid, coccidiosis, pneumonia, and diseases of the digestive tract of poultry, whereas the article was not so effective.

The amended libels further alleged that the booklets and the leaflet accompanied the articles when they were introduced into and while they were in interstate commerce in the following manner: That a number of copies of the booklets and the leaflet was received by the consignee at Worthington, Minn., from Dr. Salsbury's Laboratories, Charles City, Iowa, on or about January 14, and April 9 and 29, 1942; that certain of the booklets and the leaflet were thereafter prominently displayed in the consignee's establishment, together with and in association with and in close proximity to the articles; that the booklets, or some of them, were distributed to purchasers of the articles; and that the shipments of the articles and the delivery and receipt of each of the booklets and the leaflet constituted transactions in interstate commerce between Dr. Salsbury's Laboratories and the consignee.

Dr. Salsbury's Laboratories, a corporation, appeared as claimant for the articles and, on or about June 8, 1943, filed answers to the amended libels denying that the articles were misbranded; that the aforesaid booklets or leaflet accompanied the articles while they were in interstate commerce; or that they ever formed a part of the labeling of the articles. The cases came on for trial on June 8, 1943, at which time a motion was granted for their consolidation and, by unanimous consent of the court and counsel, an order was entered for the continuance of the matter. Thereafter a stipulation of facts was filed by the parties, after which a motion to dismiss the libels for lack of jurisdiction over the subject matter was submitted by the claimant. On September 13, 1943, an order was made denying that motion and on September 14, 1943, the case came on for trial before a jury. The trial was concluded on September 28, 1943, with the jury returning verdicts for the Government. On October 8, 1943, judgments of condemnation were entered against the above-named products and it was ordered that they be destroyed on or before November 9, 1943. On October 15, 1943, execution of the judgments was stayed to permit consideration of a motion which had been filed by the claimant for a new trial, and on October 30, 1943, oral argument on this motion was held, after which the matter was taken under advisement by the court for consideration of the arguments and briefs of counsel. On January 31, 1944, an order was entered in denial of the motion, accompanied by the following memorandum opinion of the court:

JOYCE, *District Judge:* "These proceedings arose as a result of libels of information filed by the United States on June 1, 1942, against certain quantities of

three articles of drug labeled in part 'Dr. Salsbury's Rakos', 'Dr. Salsbury's Phen-O-Sal', and 'Dr. Salsbury's Can-Pho-Sal', charging that these articles were misbranded in violation of the Federal Food, Drug and Cosmetic Act (21 U. S. C. section 301, et seq) and subject to seizure and condemnation. A monition was issued and the United States Marshal pursuant thereto attached the articles in the possession of Boote's Hatcheries and Packing Company, Worthington, Minnesota, hereinafter called 'the Hatcheries', where they had been shipped on various dates after January 1, 1942, by Dr. Salsbury's Laboratories, Charles City, Iowa, hereinafter called 'the Laboratories'. Thereafter the Laboratories intervened as claimant. As a result of preliminary proceedings, amended libels were filed by the United States. Each of the amended libels charged that the three articles were misbranded in violation of Section 502 (a) as a result of the association between the articles and five printed booklets. * * * These booklets, which are alleged to contain false and misleading representations concerning the effectiveness of the three articles in the treatment of specified diseases of poultry, were delivered to the Hatcheries by a sales representative of the Laboratories, and are alleged to have accompanied the articles in interstate commerce so as to constitute 'labeling' as defined in Section 201 (m) (2) of the Act. Each of the libels has attached as exhibits such portions of these booklets as the government alleged were false and misleading. Answers filed by the claimant denied that the booklets constituted 'labeling', denied that they contained false and misleading representations as to their effectiveness, and alleged that the three articles were not subject to seizure and condemnation under Section 304 (a) of the Act.

"In order that the court might pass upon the questions of whether the booklets are 'labeling' and whether the drugs are subject to seizure and condemnation, the parties stipulated the relevant facts. Claimant then moved to dismiss the libels upon the ground that the stipulation established that the articles of drug were not misbranded 'when introduced into or while in interstate commerce' as required by Section 304 (a), and, therefore, this court had no jurisdiction over the subject matter of these proceedings. On September 13, 1943, an order was made denying this motion.

"The three cases were consolidated for trial before a jury, and verdicts in favor of the United States were returned. The jury specially found that the three articles were misbranded. Appropriate decrees of condemnation and orders for destruction were submitted and approved. Claimant has now moved for new trials in each of the three cases and has assigned forty-five grounds of error.

"It is proper that consideration first be given to those specifications of error which attack the propriety of the order denying the motion to dismiss the proceedings for want of jurisdiction over the subject matter. Although the stipulation specifically applies to Civil 125, involving the product Rakos, the parties have agreed that it is also typical of and applicable to Civil 126 and 127, involving the products Phen-O-Sal and Can-Pho-Sal.

"From the stipulation it appears that the Laboratories is an Iowa corporation which distributes throughout the United States a line of poultry remedies designed for the prevention and treatment of diseases of poultry. Main offices are located at Charles City, Iowa, with branches at Columbus, Ohio, Forth Worth, Texas, and Kansas City, Missouri. Employing over 300 persons, the firm had sales in 1941 exceeding one million dollars. Distribution of its remedies is through hatcheries, drug stores, and feed and poultry houses, serviced by salesmen making regular calls.

"One such salesman is Mr. A. F. Achilles, a resident of St. Paul, whose sales territory includes Worthington, Minnesota, where the Hatcheries are located. Since his employment on January 1, 1937, Achilles has made monthly calls on dealers in his territory in the solicitation of orders and rendering poultry services. Several times yearly, printed matter is shipped to Mr. Achilles by the Laboratories for distribution to his customers. In calling upon dealers, Achilles furnished them, 'according to their needs and requirements and out of a supply carried in his car,' with the type of booklets here involved. 'Generally, Mr. Achilles, as part of his duties, on each of his regular calls on dealers, would determine whether sufficient quantities of the said booklets were on hand, and where the supply was low, it would be replenished out of supplies carried by him. Occasionally, a dealer, in order to maintain an adequate supply, would inform Mr. Achilles of his need for the said booklets without waiting for Mr. Achilles to check the quantity on hand.' Where dealers desired replenishment of their stock of booklets prior to Achilles' monthly visit, request would be made upon

the Laboratories, 'sometimes in connection with an order for merchandise,' and a supply would either be delivered by Achilles or sent in small quantities from Charles City, Iowa. 'During the spring and fall of each year as desired, a dealer would be provided by Mr. Achilles with window, counter, wall, and floor display cards and posters.'

"It further appears from the stipulation that the quantities of the product Rakos here involved were shipped in interstate commerce from Charles City, Iowa, via railroad, on January 16 and April 11, 1942, and via truck express, on May 4, 1942, to the Hatcheries at Worthington, Minnesota. Prior to these times, the booklets here involved had been shipped and cause to be shipped in interstate commerce by the Laboratories to Achilles at St. Paul, Minnesota. These were delivered by Achilles to the Hatcheries on January 14, 1942, and April 29, 1942, 'where they were prominently displayed together with, in immediate proximity to and in association with various articles of drugs manufactured and sold by Dr. Salsbury's Laboratories including specifically the articles of drug labeled in part 'Dr. Salsbury's Rakos' (including that quantity seized herein),' 'Dr. Salsbury's Phen-O-Sal,' and 'Dr. Salsbury's Can-Pho-Sal', and were available for reading and accessible for distribution with the sale, actual or potential, of these articles of drugs. The posters and display cards of the type herewith submitted as Exhibits A through E, which had been delivered by Mr. Achilles prior to the dates specified herein, were similarly displayed.'

"It is also stated that in addition to being displayed and available with the drugs, the booklets 'are distributed by dealers . . . in over the counter transactions with purchases of one or more of the articles of drugs manufactured and sold by Dr. Salsbury's Laboratories including the articles of drug labeled in part, 'Dr. Salsbury's Rakos', 'Dr. Salsbury's Phen-O-Sal', and 'Dr. Salsbury's Can-Pho-Sal'. Also, a store patron may freely avail himself of one or more of the said booklets even though making no purchase.' It is also agreed that the principal distribution of Government's Exhibit 5, several million annually, is by direct mailing to farmers throughout the United States at the request of dealers. These are mailed from Mount Morris, Illinois, where they are printed.

"The following provisions of the Act are pertinent to claimant's contention. Section 502 (a), defines misbranding as follows: 'A drug or device shall be deemed to be misbranded—(a) If its labeling is false or misleading in any particular.' 'Labeling' is defined by section 201 (m) (2) to mean 'all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.' So far as applicable, Section 304 (a), provides that 'Any article of . . . drug . . . that is . . . misbranded when introduced into or while in interstate commerce . . . shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found . . .'

"The specific contention made by claimant is that the stipulation establishes that while the quantities of Rakos here involved were shipped on January 16, April 11, and May 4, 1942, the booklets had been shipped to Achilles prior thereto, and were delivered to the Hatcheries on January 14, and April 29, 1942. Therefore, there is said to be a complete lack of identity as to times of shipment, times of arrival and routes travelled between the drugs and the booklets. Accordingly, it is argued, the drugs were not misbranded 'when introduced into or while in interstate commerce' as required by Section 304 (a).

"In passing upon this contention, of paramount importance is the fact that the Federal Food, Drug & Cosmetic Act is an enactment under the Commerce Clause. Accordingly, in construing its provisions, consideration should be given to the purposes of the Act, its history, the specific terminology used therein and the enforcement procedures adopted. *Kirschbaum* v. *Walling*, 316 U. S. 517, 520. The history behind the present Act dates from 1906 when the Food and Drugs Act was adopted. 21 U. S. C., Sec. 1, et seq. One of the most important enactments under the Commerce Clause, its purposes of protecting the public health and pocketbook against adulterated and misbranded foods and drugs, have led courts to declare with unanimity that food and drug legislation should be given a liberal construction in order to accomplish its remedial purposes. *United States* v. *95 Barrels of Vinegar*, 265 U. S. 438; *United States* v. *Antikamnia Chemical Co.*, 231 U. S. 654, 655; *United States* v. *Schider*, 246 U. S. 519, 522; *Wm. M. Galt Co.* v. *United States*, (1913) 39 App. D. C. 470; *United States* v. *Research Commercial Creamery Co.*, (D. C. Wash. 1942) 43 F. Supp. 714, 715.

"Stating the basis for the enactment of the 1906 Act, the Court in *Hipolite Egg Co.* v. *United States*, 220 U. S. 45, 57, said: 'The statute rests, of course, upon the power of Congress to regulate interstate commerce; and, defining that power, we have said that no trade can be carried on between the states to which it does not extend, and have further said that it is complete in itself, subject to no limitations except those found in the Constitution.' That Congress was regulating what it regarded as illicit articles of commerce was made equally clear: 'We are dealing, it must be remembered, with illicit articles—articles which the law seeks to keep out of commerce because they are debased by adulteration, and which punishes them (if we may so express ourselves) and the shipper of them.' 220 U. S. at p. 57. In the case of adulterated articles, this illicit quality was supplied by the presence of a deleterious substance in the article (*Hipolite Egg Co.* v. *United States*, supra) and in the case of misbranding, it was supplied by the presence of a false label on the article. *McDermott* v. *Wisconsin*, 228 U. S. 115, 131–133. 'The object of the statute is to prevent the misuse of the facilities of interstate commerce in conveying to and placing before the consumer misbranded and adulterated articles of medicine or food.' 228 U. S. p. 131. The remedy of seizure and condemnation was said to be an appropriate means for preventing the transportation of such articles. *Hipolite Egg Co.* v. *United States*, 220 U. S. pp. 57–58.

"Inasmuch as Congress was dealing with what it regarded as illicit articles of commerce, it is not surprising that under the 1906 Act, the concept of misbranding was limited to the label or brand appearing upon the article or package. Accordingly, under Section 8 of the 1906 Act, an article was misbranded if 'the *package* or *label* . . . shall bear any statement, design, or device regarding such article, or the ingredients or substances contained therein which shall be false or misleading in any particular.' (Emphasis supplied.) Any article so labeled was illicit in commerce. 'The label is the means of vindication or the basis of punishment in determining the character of the interstate shipment dealt with by Congress'. *McDermott* v. *Wisconsin*, 228 U. S. p. 133.

"It soon became apparent, however, that this concept of misbranding was too narrow. Thus a manufacturer could make false claims on a circular enclosed in the package containing the article without misbranding it under the phraseology of Section 8. *United States* v. *American Druggists' Syndicate* (C. C. N. Y. 1911), 186 Fed. 387; *United States* v. *Newton Tea & Spice Co.* (D. C. Ohio 1920), 275 Fed. 394. Congress in 1912 endeavored to correct this deficiency by passing the Sherley Amendment which defined as misbranded any article whose 'package or label shall *bear* or *contain* any statement, design, or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein, which is false and fraudulent.' (Emphasis supplied), 21 U. S. C., Sec. 10 Third). The attack upon the constitutionality of this amendment was considered in *Seven Cases* v. *United States*, 239 U. S. 510. The Supreme Court decided that circulars bearing false and fraudulent therapeutic claims enclosed within the package containing the article would now misbrand it. Just as the label, under the 1906 Act, conferred upon the article its illicit character in commerce, so now the circular under the 1912 amendment provided this status. 'The false and fraudulent statement . . . in the package . . . gives to the article its character in interstate commerce.' 239 U. S. p. 517.

"So prior to 1938, the law protected the public only where false claims were made on the label or package or in a circular within the package. Accordingly, to avoid the jurisdiction of the Food and Drug Administration, a patent medicine manufacturer needed only to separate physically the printed matter bearing the false claims from the article itself. This and other deficiencies in the old Act resulted in its complete overhauling by Congress and culminated in the enactment in 1930 of the present Act. The avowed objective of the new Act was to strengthen the protection afforded the public by eliminating the loopholes and expanding consumer protection. Cong. Rec. 73rd Cong. 2nd session, Vol. 78, Part 5, pp. 4567–4573. Many new provisions were added and old ones enlarged. The concept of misbranding was expanded to include any drug whose 'labeling' is false or misleading. 'Labeling' comprehends labels, container wrappers, and all written, printed and graphic matter which accompanies any article of food or drug. Enforcement procedures were expanded by the inclusion of new prohibited acts and injunctive relief. (See Section 301, 303). The seizure and condemnation provisions were modified to eliminate obstacles to effectiveness and their availability was enlarged. (Compare Section 10, 1906 Act, with Section 304 (a), 1938 Act.)

"It is perfectly clear that to resolve the present controversy it is necessary to consider the interrelation of Sections 201 (m) (2) defining labeling, 502 (a)

defining misbranding, and 304 (a) providing for seizure and condemnation. Unless an article of drug is misbranded when it enters or while in interstate commerce, seizure is unavailable. There is no misbranding unless its labeling is false or misleading. Printed matter is labeling and will misbrand if it appears on the article, in the package or accompanies the article and is false or misleading in any particular.

"Realizing that Congress was attempting to expand the protection given consumers in redefining the concept of misbranding, it is evident that the word 'accompany' should be given an interpretation which accords with the Congressional purpose. There is evidence in the legislative history of the labeling section indicating that broad coverage was intended. Thus in addressing the Senate committee in regard to this section, W. G. Campbell, Commissioner of the Food and Drug Administration, stated: 'The term 'labeling' is defined so as to include not only the label but all circulars and material and placards for display purposes and the like that may in any form whatever accompany the article of food, drug or cosmetic . . . .' United States Senate Report 1944, 73rd Cong. 2nd Session, p. 16. There is nothing elsewhere in the history which in any way indicated that anything less than that was intended.

"The narrow question here is the extent to which printed matter must 'accompany' articles of drug at the time of introduction into or while in interstate commerce in order that such articles can be said to be 'misbranded' within the meaning of Section 304 (a). In answer to this question, the government states that the old physical contiguity test of misbranding operative under the old law has been discarded and the present act should be given the broadest possible interpretation in accomplishing the consumer protection intended by Congress. Claimant states that it does not believe that physical annexation between the drug and printed matter is always necessary, but insists that because there are differences in times of shipment, times of delivery and routes travelled, the drugs here seized could not possibly have been 'misbranded' at any time in their interstate journey.

"The provision in Section 304 (a) that an article to be subject to seizure must have been 'misbranded' during its interstate journey is the counterpart in the present Act of the theory and terminology of Section 10 of the old Act (21 U. S. C. Sec. 14). Thereunder, seizure was available as to any 'article of . . . drug . . . that is . . . misbranded . . . and is being transported from one State . . . to another . . .' Since the concept of misbranding was then limited to printed matter physically contiguous with the article, necessarily there was an actual physical misbranding throughout the interstate journey. However, as we have seen, the concept of misbranding has now been extended by Congress beyond this restricted notion of physical contiguity. Since Congress should not be thought to have expanded the substance without expanding the remedy, in asking whether an article is 'misbranded' in commerce as required by Section 304 (a), we must necessarily apply the enlarged concept which the law has now created. The full scope of the present concept of misbranding must be applied in the interpretation of Section 304 (a). As we have seen, Congress was dealing in this legislation with articles which were regarded as illicit. Accordingly, just as it was the label in 1906 and the circular in 1912 which conferred upon an article its misbranded status in commerce, so now under the present Act, printed matter which can be said to have accompanied an article confers its misbranded status in commerce.

"Aside from the theory of the food and drug legislation, it is manifest that misbranding has true significance only in terms of the consumer. It matters little whether a farmer goes to Boote's Hatcheries and sees a large display card proclaiming the benefits of Rakos in the treatment of coccidiosis, or finds the same matter actually upon the carton or label of the product. If such representations are false, he is as much defrauded irrespective of the location of the printed statement. Nor does it matter to the farmer whether the booklets were physically side by side with bottles of Rakos during the interstate journey, or were delivered by a salesman. When the farmer enters a dealer's store, he finds the Rakos and the booklets together in one indivisible merchandising unit. Nothing on the bottle of Rakos, or on or in the carton in which it is sold tells the farmer that Rakos shall be used in the treatment of coccidiosis. The only statements to that effect are found in booklets displayed and distributed with Rakos and upon placards and wall posters prominently arranged in the store. The fact that the farmer has suffered an out-of-pocket loss by relying upon these representations should not be obscured by any

subtle inquiries concerning whether the printed representations rode with the drugs on the same train, at the same time or over the same route.

"In support of its claim that seizure and condemnation are available here, the Government has made three contentions. First, it claims that if printed matter at any time after an interstate shipment of drugs comes into a relationship which complies with the requirements of 'labeling', the misbranding which then occurs is retroactively effective from the moment the drugs entered the channels of commerce. Although the use by the drugs of the facilities of commerce seemingly is proper, yet the end result was the misbranding which Congress sought to avoid, and this wrong was a wrong ab initio. Second, the Government contends that the stipulation establishes that the drugs were 'misbranded' in commerce because the facts show that the booklets did actually accompany the drugs in commerce. Third, the Government contends that the booklets and drugs were part of one interstate transaction, and that 'commerce among the states is not a technical legal conception, but a practical one, drawn from the course of business.' *Swift & Co.* v. *United States*, 196 U. S. 375, 398. Since I concur in the correctness of the second contention, it is unnecessary to consider either of the other arguments.

"In essence the question is: Must there be physical accompaniment throughout the entire interstate movement of the drugs in order for seizure and condemnation to be available? The question is answered in the negative. So to hold would be to resurrect the physical proximity theory of misbranding. May not an article be 'misbranded' in commerce within the meaning of Section 304 (a) by printed matter which, though not physically contiguous thereto, nevertheless actually did 'accompany' the article for all practical purposes and in all significant aspects? This question is answered in the affirmative.

"The answer to these questions was first made in *United States* v. *Research Laboratories*, (C. C. A. 9, 1942) 126 F. (2d) 42, where the libel, which the lower court dismissed, alleged that the circulars accompanied the articles in commerce by having the same origin and in simultaneously arriving with the articles at destination where they were placed in the same room in the consignee's warehouse. In reversing the lower court, the court said: 'The libel does not state, nor is it material, whether the packages and the circulars did or did not travel in the same crate, carton or other container or on the same train, truck or other vehicle during their interstate journey. The packages and the circulars had a common origin and a common destination and arrived at their destination simultaneously. *Clearly, therefore, they accompanied each other, regardless of whether, physically, they were together or apart during their journey.*' (Emphasis supplied). The principle of that case in rejecting the concept of physical contiguity as a test for misbranding under Section 304 (a), in my opinion is sound. Once this principle is comprehended, it is simply a question of determining in a given case whether the relationship between the article and the printed matter is sufficiently proximate to fulfill the requirements of accompaniment.

"The word 'accompany' as used in Section 201 (m) (2) was said in *United States* v. *Lee*, (C. C. A. 7, 1942) 131 F. (2d) 464, 466, to mean: 'The word 'accompany' is not defined in the Act, but we observe that among the meanings attributed to the word are 'to go along with,' 'to go with or attend as a companion or associate,' and 'to occur in association with, Webster's New International Dictionary, 2d Ed.' Naturally, meanings of accompany will vary in connection with subject matter 'Accompany' as used in this Act is used to describe a relationship between an article of drug and its labeling. Since there 'can be no question that among the usual characteristics of labeling is that of informing a purchaser of the uses of an article to which the labeling relates' (*United States* v. *Lee*, at p. 466), the booklets here involved should be scrutinized from this viewpoint. In the sense just stated, if the booklets are not labeling, then the products Rakos, Phen-O-Sal and Can-Pho-Sal have none.

"The stipulation clearly shows that the printed matter and the drugs had a common origin. They had a common destination in that both were intended to come together in the stores of dealers in Achilles' territory. They were interlocking units of a distributional scheme the objective of which was ultimate association and distribution together. There was actual, physical association together in the stores of dealers and actual distribution together in connection with purchases by farmers. It is fair to conclude that these booklets were prepared, shipped and distributed to dealers with the ultimate expectation and intention on the part of the Laboratories that they would serve the purpose of labeling for the three articles of merchandise here involved. Without the book-

lets, the products themselves lacked labeling, at least in so far as informing purchasers of the purposes and uses of the remedies. The mere fact that the products were shipped at a different time, over a different route and were received at a different time from the booklets should not be permitted to confuse or obscure the substance of the matter. The instant that the product Rakos entered the channels of commerce enroute to the Hatcheries, it was to all intents and purposes as much travelling in accompaniment of the representations contained in the booklets as if those booklets were actually enclosed in the same shipping container. It is unquestionable that both the drugs and the booklets used the facilities of interstate commerce to accomplish a defrauding of the public. For this transgression, the products are subject to seizure and condemnation.

"Were not the factors just stated to be given primary consideration, there would be a multiplication of refinements. Starting with the case of a circular in the package or in the shipping carton containing the drug, there would be a question as to circulars in a different car on the same train, or a different train, at a different time, over a different route, or by a different type of carrier. The physical aspects of the transportation are not important. What is vital here are such factors as interdependence of the drug and the booklets, common origin, common destination, display, distribution and use together. These determine whether there has been that degree of accompaniment which provides the necessary 'misbranded' status under Section 304 (a). The mere fortuitous circumstance of an absence of physical association between the booklets and drugs during the interstate journey of the drugs does not in my opinion control.

"Claimant insists, however, that there is no occasion for employing seizure and condemnation in this situation as the Government has a right to proceed by injunction under Section 301 (k).[1] Claimant states that this section authorizes the Government to enjoin the Laboratories from causing an association between the printed matter and the drugs at the retailer's place of business. *United States* v. *Lee*, supra. The Government, however, does not concede that this section is necessarily available here and suggests several arguments which claimant might have made as to the non-applicability of Section 301 (k) had the Government attempted to use it.

"This Court does not in this proceeding propose to mark out the limits of Section 301 (k). Seemingly, however, it was enacted by Congress under its authority to regulate activities affecting interstate commerce. See *Labor Board* v. *Jones & Laughlin*, 301 U. S. 1. In referring to alteration, mutilation, destruction, obliteration or removal of labels this section at least suggests the possibility that what it contemplates is a lawful use by a drug of the facilities of interstate commerce followed by some activity which causes it to be misbranded. In the instant case, drugs and booklets were flowing through commerce in a relationship which has been found to make illegal the use by the drugs of the facilities of commerce. In any event, in absence of further clarification, it cannot be said that the applicability of Section 301 (k) to the facts set forth in the stipulation is so clear that doubts should be entertained as to the applicabilty of Section 304 (a).

"The ground of error most vigorously asserted by claimant in its motion goes to the failure of the court to grant certain requested instructions. Requests 3 and 4 were as follows:

" 'The law under which this proceeding is instituted does not contemplate that statements with reference to the curative or therapeutic value of the drugs shall be deemed false or misleading with respect to matters as to which there is an honest difference of opinions between schools and practitioners.

" 'In the treatment of diseases of animals honest differences of opinion may arise between school and practitioners as to the therapeutic or curative value of drugs. Statements with reference to the curative value of drugs or helpfulness in assisting in bringing about a cure are not to be deemed false and misleading merely because differences of opinion exists between different groups of Veterinarys, or different groups skilled in this particular line of endeavor as to the curative value.'

[1] The full text of Sec. 301 (k) is as follows: "The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded."

"Failure to grant these requests is said to have constituted unconstitutional application of Section 502 (a), for the reason that it permitted the jury to find claims of effectiveness to be false and misleading upon the basis of differences of expert opinion. Failure to charge as requested is said to have permitted the jury to weigh differences of expert opinion and to decide whether the claims of effectiveness made by claimant were false or misleading depending upon whether it followed the experts for the Government or those for claimant. This, it is said, introduced such uncertainty into Section 502 (a) as would make it void for uncertainty. Cases cited in support thereof are *American School of Magnetic Healing* v. *McAnnulty*, 187 U. S. 94; *United States* v. *Johnson*, 221 U. S. 488; *Seven Cases* v. *United States*, 239 U. S. 510, and cases holding that a statute must define an offense with reasonable certainty in order that a person may know what is prohibited. *United States* v. *Cohen Grocery Co.*, 255 U. S. 81; *Connally* v. *General Const. Co.*, 269 U. S. 385.

"The law under which these proceedings were instituted provides that a drug is misbranded if its labeling is false or misleading in any particular. There is nothing in this standard which is vague or indefinite. It prescribes a rule of conduct by which persons can measure their acts. In and of itself there is and can be no contention that the provisions of Section 502 (a) are void for indefiniteness and uncertainty. *United States* v. *Cohen Grocery Co.*, supra; *Connally* v. *General Const. Co.*, supra; *Coplin* v. *U. S.* (C. C. A. 9, 1937) 88 F. (2) 652, 657.

"Claimant, however, supports its contention that the standard is uncertain and indefinite by adding another element, the difference of opinion between the experts appearing for the Government and those appearing for claimant. It is said that the question of 'whether or not these remedies are of value in the treatment of poultry diseases involves a question of opinion and not a strict question of fact'. Therefore, it is concluded, refusal to charge the jury as requested in 3 and 4 placed an unconstitutional interpretation upon Sec. 502 (a) by allowing the jury to find the claims of effectiveness false or misleading by deciding between two groups expressing different opinions about the effectiveness of these remedies.

"Implicity, the argument for claimant proceeds upon the assumption that it would be beyond the power of Congress to permit a claim of effectiveness to be found false by a jury where medical or veterinary opinion is divided on the matter. Whatever the merit of this assumption, it is clear that Congress has not attempted to do this in Section 502 (a), nor did it do so in prior legislation. What Congress had done is to permit a claim of effectiveness to be found false or misleading where the question of effectiveness is demonstrable as a fact. I do not think that I have permitted more in these proceedings.

"The law is regarded to the effect of a difference of medical opinion upon a proceeding in which a claim of effectiveness is sought to be proved false stems from *American School of Magnetic Healing* v. *McAnnulty*, 187 U. S. 94. In that case, the Postmaster General upon the basis of evidence satisfactory to him, issued a fraud order upon the ground that the Magnetic Healing School was using the mails to obtain money by means of false and fraudulent pretenses. An injunction was sought to restrain the Postmaster from carrying out the terms of the fraud order. A demurrer to the bill was sustained in the lower court and reversed on appeal. Laying constitutional consideration to one side, the Supreme Court held that the School's claims of effectiveness for its method of treatment of diseases, as to which there was a difference of medical opinion, could not be condemned as false for the reason that, being based upon differences of opinion, there was no standard of fact or truth by which to measure the falsity of the claims. The court stated that efficacy of treatment was a matter of opinion entirely and not a matter of absolute fact capable of proof as a fact. Under the statute, the Postmaster General was said to have no authority to decide between the conflicting opinions. The Court held that where variant opinions appear as to claims of effectiveness, such a statute does not apply as a matter of law.

"Later cases made the McAnnulty rule applicable to food and drug legislation under which statements constituted misbranding where false or misleading in any particular (1906 Act), or false and fraudulent (1912 Amendment), as applied to curative claims. *United States* v. *Johnson*, 221 U. S. 488; *Seven Cases* v *United States*, 239 U. S. 510. Although the majority of the court in the Johnson case believed that Section 8 of the 1906 Act in declaring as misbranded statements which were false or misleading applied only to statements of strength,

identity, quality and purity and did not apply to claims of curative value, and intimated that Congress was unlikely to distort its constitutional power to establish criteria in regions where opinion is wide apart, yet it is significant that the decision does not rest upon a constitutional basis. It was simply decided that Section 8 was not intended to apply to expressions of curative value. Following this decision, Congress amended the 1906 Act expressly to provide that statements of curative value would constitute misbranding if 'false and fraudulent'. When the constitutionality of this amendment was attacked upon the same ground as claimant advances here, a unanimous court in *Seven Cases* v. *United States* held that the amendment was intended to apply not to expressions of opinion but only to expressions of effectiveness which were plainly contrary to fact.

"Although the court in the McAnnulty case had said that assertions of effectiveness were always matters of opinion because 'There is no exact standard of absolute truth by which to prove the assertion false and a fraud . . . [since] . . . the claim . . . cannot be the subject of proof as of an ordinary fact,' 187 U. S. 104, the court now states that there is a category of assertions which fall outside the field of opinion and into the field of fact. 'Congress deliberately excluded the field where there are honest differences of opinion between schools and practitioners . . Congress recognized that there was a wide field in which assertions as to curative effect are in no sense honest expressions of opinion, but constitute absolute falsehoods.' *Seven Cases* v. *United States*, 239 U. S. p. 517. In view of the fact that Justice Hughes, who spoke for a unanimous court in *Seven Cases* v. *United States*, dissented from the majority opinion in the Johnson case as to the scope of Section 8 of the 1906 Act, the language which he used in his dissent is of significance upon this question. He stated, 'It is, of course, true, that when Congress used the words 'false or misleading statement,' it referred to a well defined category in the law, and must be taken to have intended statements of *fact*, and not mere expressions of opinion . . . But, granting the widest domain of opinion, and allowing the broadest range to the conflict of medical views, there still remains a field in which statements as to curative properties are downright falsehoods and in no sense expressions of judgment. This field I believe this statute covers.' 21 U. S. p. 504. In using this language, Justice Hughes was referring to terminology in the 1906 Act which is in all respects identical with that contained in Section 502 (a).

"Plainly, therefore, the subject of regulation in the 1938 Act, as in its predecessors, is matter of fact, not matter of opinion. See House Committee Report No. 2139, 75th Congress, 3d Session. Except as affected by Section 201 (n) and the regulations issued thereunder, it is clear that food and drug legislation was intended to apply only to false or misleading expressions of fact. It seems manifest that the question of whether a remedy is effective is always a question of fact. A remedy cannot be both effective and ineffective under identical circumstances. The susceptibility of effectiveness to proof as a fact necessarily determines whether assertions can be adjudged false or misleading within the meaning of Section 502 (a). Necessarily, therefore, whether in a given case the question of effectiveness is one of opinion or fact depends entirely upon the evidence which is introduced.

"Under the law as it now exists, before a court is warranted in submitting the false or misleading qualities of an assertion of effectiveness to a jury to decide, it must be satisfied that something more is involved than mere difference of opinion between schools or practitioners. As stated by Justice Hughes in his dissent in the Johnson case, 'I entirely agree that in any case brought under the act for misbranding—by a false or misleading statement as to curative properties of an article—it would be the duty of the court to direct an acquittal when it appeared that the statement concerned a matter of opinion. Conviction would stand only where it had been shown that, apart from any question of opinion, the so-called remedy was absolutely worthless, and hence the label demonstrably false,' 221 U. S. 507. If the evidence is such that it appears that the question of effectiveness has not transcended the realm of opinion into the realm of demonstrable fact, the court must hold as a matter of law that assertions of effectiveness are not false and refuse to submit the question to the jury. *American School of Magnetic Healing* v. *McAnnulty*, supra; see *L. B. Silver* v. *Federal Trade Commission* (C. C. A. 6, 1923), 289 Fed. 985; cf. *Bruce* v. *United States*, (C. C. A. 9, 1912) 202 Fed. 98. But where the evidence indicates that there is a standard of demonstrable truth and fact by which the jury can measure the claims of effectiveness, the court should then submit the question to the jury under appropriate instructions. What the evidence shows in a given case is a question of law for the court to decide.

"In light of these considerations, it appears that the claims of unconstitutionality made by claimant as to the interpretation given to Section 502 (a) in the charge are not well taken. The only situation where claimant could possibly say that its claimed constitutional rights had been invaded would be where a court had permitted the jury to find a claim of effectiveness false on the basis of evidence which indicated only a contrariety of opinion. No possible question of constitutionality can arise in a case where the evidence upon which the question of effectiveness was decided by the jury has the necessary factual basis. Such factual proof was present at the time these cases were submitted to the jury.

"Scientific witnesses for the Government in this case made elaborate and comprehensive tests of claimant's remedies under conditions most favorable to the remedies. Practically all of the experts testifying for the Government had conducted significant experimentation either in the field or in the laboratory. In the experimentation, all factors were controlled and a complete identity of circumstances and environmnet for the experimental poultry was provided. The report of such tests showed conclusively that the remedies were absolutely worthless and without any benefit whatsoever. The infected, untreated experimental group showed the same rate of mortality and recovery as the infected, treated group. These tests were duplicated and corroborated away from the laboratory under so-called field conditions. These tests were recognized by outstanding men of science as constituting conclusive evidence by recognized scientific standards that the remedies were wholly ineffective.

"Facts established by recognized scientific investigation are deserving of high standing in respect to the falsity of claims of effectiveness. *Elliott Works* v. *Frisk*, (D. C. Iowa 1932) 58 F. (2d) 820, 824–825; cf. *United States* v. *Lesser*, (C. C. A. 2, 1933) 66 F. (2d) 612, 616. Moreover, it must be obvious that tremendous advancements in scientific knowledge and certainty have been made since the rule in the McAnnulty case was first announced. Questions which previously were subjects only of opinion have now been answered with certainty by the application of scientifically known facts. In the consideration of the McAnnulty rule, courts should give recognition to this advancement.

"None of the experimental data introduced by claimant in any way directly or completely opposed the conclusiveness of the experimentation conducted by Government experts, and the jury was entitled to find that it was lacking in significance. It is true that claimant produced veterinarians from its own organization and from other remedy companies who expressed the opinion that these remedies were effective. But it is unthinkable that this expression of opinion by these so-called experts could in any way operate to prevent these cases from being submitted to the jury or to require the court to instruct the jury to ignore all expressions of opinion on the part of both sides.

"But the requested instructions did not in any way raise these issues. The requests did not ask the court to instruct the jury to ignore all opinion testimony. As the summation by claimant's counsel indicated, claimant was perfectly willing that the jury should have the benefit of the opinions rendered by its experts that these remedies were effective. Accordingly, the jury was instructed that the issue of misbranding, i. e. the question of effectiveness, should be decided upon a consideration of all the testimony. Certainly where factual proof is present which indicates the worthlessness of the remedies in question, mere injection of an alleged difference of opinion on the part of persons whom the jury might find were either ignorant or charlatans, could not operate to prevent the jury from deciding the question of effectiveness. Under the evidence in this case, the jury was entirely warranted in finding that the contrary expressions of opinion by the witnesses appearing for claimant were in direct opposition to established scientific fact.

"The only possible question which claimant's requests raised was whether there was in the evidence any more than mere difference of opinion between groups of veterinarians. Since there was abundant factual evidence of ineffectiveness, the requests served no purpose and were therefore refused. Certainly there was no occasion for telling the jury about what the rule would have been had the evidence been different than it was.

"Failure to give other requested instructions is also assigned as error. These asked that the jury be told that the booklets did not represent that the remedies would cure, but merely indicated that the remedies would be helpful. Also, requests were made as to what degree of helpfulness a drug must have in order that it possess therapeutic or curative properties.

"The libels in this case charged that the representations contained in the booklets were false and misleading because they represented that the remedies were effective in the treatment of poultry diseases when they were not effective. Whether they were represented to be effective and whether they were effective were the issues in the case. The testimony for the Government, acquiesced in by three witnesses for claimant, was that before these remedies could be effective, a capacity to destroy or inhibit germs was necessary. Under this state of the evidence, it was unnecessary to tell the jury about what would be necessary for the remedies to be curative or therapeutic. Whether the statements appearing in the booklets represented the remedies to be effective was for the jury to say in light of the ordinary meaning of the language used. *Bradley* v. *United States*, (C. C. A. 5, 1920) 264 Fed. 79; *Hall* v. *United States*, (C. C. A. 5, 1920) 267 Fed. 795; *United States* v. *John J. Fulton Co.*, (C. C. A. 9, 1929) 33 F. (2d) 506.

"Claimant assigns as error the action of the court in permitting the experts for the Government to testify as to the ultimate issues in the case, citing *United States* v. *Spaulding*, 293 U. S. 498. All of the opinion evidence given by the Government's experts necessarily involved the use of their experience and training on matters of special knowledge not within the grasp of the untutored. Clearly, it would seem not improper for the court to permit them to express opinions upon the question of the effectiveness of claimant's remedies. *Dr. J. H. McLean Medicine Co.* v. *United States*, (C. C. A. 8, 1918) 253 Fed. 694; *Eleven Gross Packages* v. *United States*, (C. C. A. 3, 1916) 233 Fed. 71; *Kar-Ru Chemical Co.* v. *United States*, (C. C. A. 9, 1920) 264 Fed. 921; *United States* v. *Chichester Chemical Co.*, (App. D. C. 1924) 298 Fed. 829. All opinions given by the experts who testified for the Government were directly or indirectly expressed in relation to this question of effectiveness and did not invade the function of the jury. Moreover, in the examination of its experts, claimant was allowed similar latitude. In fact, in an effort to permit claimant to present to the jury everything which could possibly be of benefit in support of its claims of effectiveness, the court allowed very great latitude in the receipt of evidence, even to the point where opinion evidence from lay persons was received. Accordingly, if any error was committed, it was in claimant's favor and it is now in no position to complain.

"Other claims of error may be summarily dismissed. I see no impropriety in instructing the jury to ignore such portions of the closing argument of claimant's counsel as attempted to impugn the Government's motives in bringing this case at the present time. There was no evidence to justify this statement. See *London Guarantee & Accident Co.* v. *Woefle*, (C. C. A. 8, 1936) 83 F. (2d) 325, 338–344. The claimed impropriety in the argument of Government counsel, if it existed, was prompted by the improper argument of opposing counsel and was not open to censure. *Chicago & N. W. Ry. Co.* v. *Kelly*, (C. C. A. 8, 1934) 74 F. (2d) 31; *Union Electric Light & Power Co.* v. *Snyder Estate Co.*, (C. C. A. 8, 1933) 65 F. (2d) 297, 301–302.

"I feel that claimant's requests to permit the jury to examine all parts of the booklets in determining whether there were representations of effectiveness was properly denied. Much of this matter was wholly unrelated to the remedies involved and would have diverted the jury from the task at hand. Request No. 18, submitted by claimant, was granted and this in my opinion was all that it was entitled to.

"Throughout the trial, evidence as to efficacy of the remedies was offered by both sides without regard to whether it related to prevention or treatment of disease. It was, therefore, entirely proper to permit the Government to amend its pleadings to embrace both. Rule 15 (b) of the Federal Rules expressly sanctions this.

"Any error in the exclusion of Exhibit P was harmless. The materiality of and foundation for this exhibit were not clearly shown. But that aside, it was offered as impeachment evidence only. In view of the admission of Exhibit Q, its only effect would have been cumulative."

On June 27, 1944, judgments were entered ordering that the products be destroyed on or before July 31, 1944. The United States marshal destroyed them on July 8, 1944.

1093. Misbranding of Schilling's Mercutol. U. S. v. 124 Bottles of Schilling's Mercutol. Default decree of condemnation and destruction. (F. D. C. No. 9412. Sample No. 9828–F.)

On February 25, 1943, the United States attorney for Southern District of Mississippi filed a libel against 124 6-ounce bottles of Schilling's Mercutol at Jackson, Miss., alleging that the article had been shipped on or about October 5

and November 7, 1942, from New Orleans, La., by M. K. Schilling; and charging that it was misbranded.

Analysis showed that the article consisted essentially of turpentine oil, gum camphor, nitrobenzene, bichloride of mercury, and calomel (mercurous chloride).

The article was alleged to be misbranded in that the statement appearing in its labeling which represented and suggested that it possessed penetrating and healing properties; that it was a remedy for lameness in horses and mules, due to all causes; that it was effective in the treatment of the disease conditions of horses and mules known as spavin, ring-bone, splint, sweeny, fistula, poll evil, wire cuts, distemper, old sores in general, and for all disease conditions affecting the feet of such animals; and that it was effective in the treatment of the skin diseases of humans known as tetter, were false and misleading since the article would not be effective for those purposes. It was alleged to be misbranded further in that it was a drug that was fabricated from two or more ingredients, and its label failed to state the quantity of bichloride of mercury contained therein; and its label also failed to state that it contained calomel, a mercury preparation, and the quantity thereof.

On November 5, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1094. Misbranding of Wel-being. U. S. v. 288 Tins and 24 Tins of Wel-being. Default decree of condemnation and destruction. (F. D. C. No. 9554. Sample No. 12942–F.)

On March 17, 1943, the United States attorney for the District of New Jersey filed a libel against 288 3-ounce tins and 24 12-ounce tins of Wel-being at New Brunswick, N. J., alleging that the article had been shipped on or about February 18, 1943, from Portland, Oreg., by the Wel-being Co.; and charging that it was misbranded.

Analysis showed that the article consisted of a finely ground, dark brown vegetable material such as linseed meal, with a small amount of salt and sugar.

The article was alleged to be misbranded in that the name of the article, "Wel-being," and certain statements in its labeling, were false and misleading since the name and statements represented and suggested that, when taken as directed by cats, dogs, pets, and fur-bearing animals, the article created a feeling of well-being and was a highly concentrated food treatment and supplement; that it was a concentrated food and tonic; that it was effective; that it would overcome itching and scratching; that it aided in body building; that it would restore energy; that it would promote a glossy coat; that it would remove intestinal parasites; that it would aid in whelping and produce vigorous litters; that it would stimulate the appetite; that it was an appetizing, nutritional concentrate; that it would prevent skin irritations due to diet deficiency; that it was effective in stubborn cases; that it would increase body weight; that it was a protective food; that it would supply needed food elements; that it was an appetizing addition to regular rations; that it would avoid starving and dangerous methods of treatment; that it would replace recognized medicinal treatments; that it was a new, simple, scientific pet treatment for any condition; that it was effective for all worms and seasonal skin infections, poor condition, watery eyes, hair falling out, lack of pep, and poor appetite; and that it would maintain good health and guard against worms. The article was not a product of the nature so represented and suggested and would not accomplish the results claimed.

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

On July 8, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1095. Misbranding of Heath's Calf Powder. U. S. v. 18 Cartons, 6 Cartons, and 3 Cartons of Heath's Calf Powder. Decree of condemnation and destruction. (F. D. C. No. 9715. Sample No. 3338–F.)

On April 2, 1943, the United States attorney for the District of Kansas filed a libel against 18 3½-ounce cartons, 6 ½-pound cartons, and 3 1-pound cartons of Heath's Calf Powder at Topeka, Kans., alleging that the article had been shipped in interstate commerce on or about February 23, 1943, by the Bovine Specialty Company, Hynes, Calif.; and charging that it was misbranded.

Analysis showed that the article contained calcium carbonate, dried blood flour, blackberry root, Krameria, gum kino, ginger root, sodium bicarbonate,

bismuth subnitrate, red gum eucalyptus, anise, oil of cloves, and gambir. It contained 43.63 percent mineral matter, consisting largely of calcium carbonate.

The article was alleged to be misbranded in that the statements appearing on the carton labels and in the circular entitled "Save the Calf," which accompanied the article, and which represented and suggested that the article was effective in the treatment of scours in calves and in other young animals; that it was effective to keep calves alive and strong, to produce better growth and better health of calves, to prevent calves from dying, and to alleviate pain and diarrhea accompanying scours; that it was an effective treatment for scours, common scours, bloody scours, and white scours; that it was effective to enable inflamed surfaces to heal; that it was effective in checking hemorrhagic and bloody scours; and that it was effective for different forms of scours and as an intestinal antiseptic, were false and misleading since the article was not so effective.

On April 6, 1943, the claimant and owner having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered destroyed.

1096. Misbranding of Kamnic Poultry Powder. U. S. v. 137 Cans of Kamnic Poultry Powder. Default decree of condemnation and destruction. (F. D. C. No. 9864. Sample 3166–F.)

On April 28, 1943, the United States attorney for the District of Nebraska filed a libel against 137 1-pound cans of Kamnic Poultry Powder at Omaha, Nebr., alleging that the article had been shipped from Kansas City, Mo., by Research Products, Inc., on or about March 10, 1943; and charging that it was misbranded.

Analysis showed that the article consisted of 35.08 percent of iron sulfate and 0.16 percent of nicotine, together with kamala, Areca, and Quassia.

The article was alleged to be misbranded in that the name "Kamnic" was misleading since it suggested that the article was composed of kamala and nicotine, two commonly used poultry remedy ingredients, whereas the article, when used as directed, furnished insignificant amounts of these two ingredients; and in that the statements appearing on its label "Contains:—* * * Iron Sulfate (Standardized) 32%, Tobacco (Nicotine 1%) 35%," was false and misleading since the article contained more iron sulfate and less nicotine than declared. The article was alleged to be misbranded further in that the statements appearing on its label, "For Flock Treatment of Poultry * * * Withhold feed for 24 hours, allowing only drinking water. For each 30 chicks, mix one heaping tablespoonful of Kamnic Poultry Powder thoroughly with one quart of bran or shorts in thin mash and give at one feeding. For mature birds increase the above dosage one half. Repeat in 24 hours. Four hours after last treatment, give four ounces Epsom Salts to each quart of drinking water," were false and misleading since such directions for use and dosage for the flock treatment of poultry, when appearing upon the label of a poultry remedy containing nicotine and kamala, represented and suggested that the product, when used as directed, was of value in the treatment of tapeworms and roundworms which infest poultry, whereas the article, when used as directed, was of no value for any species of worms which infest poultry, nor of any value whatever as a treatment for any known disease conditions of poultry.

On May 25, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1097. Misbranding of General Hog Liquid. U. S. v. 46 Bottles, 9 Bottles, and 9 Jugs of General Hog Liquid. Default decree of condemnation and destruction. (F. D. C. No. 9838. Sample Nos. 37845–F, 37846–F.)

On April 22, 1943, the United States attorney for the Eastern District of Illinois filed a libel against 46 8-ounce bottles, 9 1-gallon bottles, and 9 5-gallon jugs of General Hog Liquid at Paxton, Ill., alleging that the article had been shipped on or about February 24 and 25 and March 8, 1943, by the General Veterinary Laboratory, Omaha, Nebr.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of water, sodium hydroxide, small proportions of compounds of calcium, copper, potassium, arsenic (60 grains per quart), creosote, oil of Chenopodium, phosphate, sulfate, and a minute amount of strychnine (0.10 gram per quart).

The article was alleged to be misbranded in that it was fabricated from two or more ingredients and its label failed to bear a statement of the quantity or proportion of strychnine and arsenic contained therein since the quantity or proportion stated was incorrect; and in that the statements "Extract of Nux Vomica (giving one quart of medicine .0266 cc. of strychnine), Solution of Potas-

sium Arsenite 59.5% (giving one quart of medicine 71 gr. of arsenic)," appearing on the label, were false and misleading since the article contained less arsenic and more strychnine than declared. The article was alleged to be misbranded further because of false and misleading statements in the circular entitled "Amazing Liquid Treats Sick, Wormy, Runty Hogs" which represented and suggested that the article was effective as a preventive and treatment for all species of worms that infest hogs; that it was effective in the prevention and treatment of sick and runty hogs, of disease germs that infest hogs, and of flu, mixed infections, and the disease known as necro; that it was effective to prevent food waste and low profits, to cause bigger litters, to raise every pig, and to bring pigs along fast and keep them free of worms and disease, to make hogs ready to sell earlier, resulting in big money and extra profits, to avoid sickness and losses, and to develop big frame and heavy bone; and that the article contained ingredients which would be effective wormers, would promote appetite in sick hogs, would be an intestinal and lung antiseptic, and would destoy germs, help in the development of big bones, purify blood, and aid digestion.

On July 9, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1098. Misbranding of Bovex. U. S. v. 21 Bottles of Bovex. Default decree of condemnation and destruction. (F. D. C. No. 9808. Sample No. 31130–F.)

Analysis showed that the article consisted of an oil such as linseed and wheat-germ oil, with a small amount of calcium carbonate and water.

On April 23, 1943, the United States attorney for the Northern District of California filed a libel against 21 1-pint bottles of Bovex at Petaluma, Calif., alleging that the article had been shipped in interstate commerce from Portland, Oreg., on or about March 23, 1943, by the Triangle Milling Co.; and charging that it was misbranded.

It was alleged to be misbranded in that the statements appearing in its label which represented and suggested that the article would be effective for better breeding; that it would promote normal breeding, aid in the prevention of sterility due to vitamin or nutritional deficiencies, aid reproduction by reason of its content of vital elements of chemicals, prevent infection, prevent the embryo from being reabsorbed, promote normal conception, reduce the immediate deficiency for normal reproduction, and help prevent reabsorption; and that vitamin E was accepted by the American Medical Association and the American Council of Pharmacy and Chemistry as the anti-sterility vitamin, were false and misleading since the article was not so effective and has not been accepted by the associations named.

The article was also alleged to be misbranded under the provisions of the law applicable to foods as reported in the notices of judgment on foods, No. 5796.

On June 30, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1099. Misbranding of medicated charcoal. U. S. v. 32 Boxes and 14 Boxes of Medicated Charcoal. Default decree of condemnation and destruction. (F. D. C. No. 9835. Sample No. 3168–F.)

On April 23, 1943, the United States attorney for the District of Nebraska filed a libel against 32 5-pound boxes and 14 10-pound boxes of medicated charcoal at Cook, Nebr., alleging that the article had been shipped in interstate commerce on or about March 5, 1943, by the Des Moines Incubator Company from Des Moines, Iowa; and charging that it was misbranded.

Analysis showed that the article consisted essentially of charcoal with Epsom salt 1.2 percent, and a very small amount, if any, of Glauber's salt. The article did not contain menthol, thymol, or methyl salicylate.

It was alleged to be misbranded in that the statement appearing on its label, "Contains: * * * Glaubers, * * * Epsom, Menthol, Methyllalicylate and Thymol," was false and misleading; and in that the statements, appearing on the box label and on the card entitled "Directions for Feeding," shipped with the article, were false and misleading since they represented and suggested that the article was effective in the prevention and treatment of white diarrhea and all other forms of digestive disturbances in chicks and fowls; that it was effective as a cure and relief for growing stock and matured fowls seriously affected with intestinal and bowel complaints and cholera; that it was guaranteed under the Food and Drugs Act of June 30, 1906; and that the use of the product would insure the raising of healthy chicks and mature fowls, whereas the article was not so effective; it was not guaranteed under the Food and

Drugs Act of June 30, 1906; and the use of the article would not insure the raising of healthy chicks and mature fowls. The article was misbranded further in that it was in package form and did not bear a label containing an accurate statement of the quantity of the contents.

On June 9, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1100. Misbranding of Miller's Liquid Hog Medicine. U. S. v. 12 Bottles and 5 Bottles of Miller's Liquid Hog Medicine. Default decree of condemnation and destruction. (F. D. C. No. 9833. Sample No. 5669–F.)

On April 23, 1943, the United States attorney for the Southern District of Iowa filed a libel against 12 1-gallon bottles and 5 3-gallon bottles of Miller's Liquid Hog Medicine at Shenandoah, Iowa, alleging that the article had been shipped on or about December 4, 1942, from Omaha, Nebr., by the Miller Chemical Co.; and charging that it was misbranded.

Analysis showed that the article consisted of water, sodium carbonate, sodium hydoxide, and sodium sulfate, with small amounts of phenolic compounds such as creosote, anise oil, and arsenic 0.012 gram per 100 cc.

The article was alleged to be misbranded (1) in that it was fabricated from two or more ingredients and its label failed to bear a statement of the quantity or proportion of potassium arsenite, a derivative of arsenic, contained therein; (2) in that the statements on the label which represented and suggested that the article was effective to aid in maintaining a normal alkaline reserve in young and old hogs and to help in building a normal body defense against intestinal infections were false and misleading since the article was not so effective; and (3) in that the label statement, "Contains * * * Arsenic 0.0048%," was false and misleading as applied to a product which contained more than twice that amount of arsenic.

On July 28, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 1051–1100

PRODUCTS

[1] Seizure contested. Contains opinion of the court.

SHIPPERS AND MANUFACTURERS

[1] Seizure contested. Contains opinion of the court.

U. S. GOVERNMENT PRINTING OFFICE: 1945

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

1101–1150

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

WATSON B. MILLER, *Acting Administrator, Federal Security Agency.*

WASHINGTON, D. C., *February 15, 1945.*

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DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS[2]

1101. Misbranding of intrauterine paste. U. S. v. Anne M. Jenks (Dependon Products and Jenks Physicians Supplies). Plea of guilty. Fine, $200 and imprisonment for 9 months. (F. D. C. No. 9627. Sample Nos. 16897–E, 16898–E, 22384–E, 22398–E.)

On June 29, 1943, the grand jurors for the District of Minnesota returned an indictment against Anne M. Jenks, doing business as Dependon Products and "Jenks" Physicians Supplies, St. Paul, Minn., alleging shipment from the State of Minnesota into the States of Missouri and California within the period from on or about September 16 to November 19, 1941, of quantities of the above-named products, which was misbranded.

Analysis disclosed that the article consisted essentially of potassium iodide, soap, alcohol, and water, and that it contained no free iodine.

The article in one of the Missouri lots and one of the California lots was alleged to be misbranded in that the statements in its labeling, "Intrauterine Paste * * * Caution—To be used only by a physician with adequate and

[1] For omission of, or unsatisfactory, ingredients statement, see Nos. 1103, 1104; omission of name and place of business of manufacturer, packer, or distributor, No. 1104; failure to bear accurate statement of quantity of contents, No. 1104; inconspicuousness of required label information, No. 1105; cosmetic, subject to the drug provisions of the Act, No. 1133.

[2] See also No. 1139 for abortifacient also alleged to be unsafe and dangerous.

continuous supervision and employing modern surgical asespis," were false and misleading since such statements represented and suggested that the article would be safe and appropriate for injection into the uterine cavity, whereas the article, whether used by a physician with adequate and continued supervision and employing modern surgical asepsis or otherwise, would not be safe and appropriate for injection into the uterine cavity, but would be unsafe and dangerous when used for such purpose, and was capable of producing serious and even fatal consequences.

The article in the remainder of the California and Missouri lots was alleged to be misbranded in that it was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in its labeling. This portion of the Missouri lots was alleged to be misbranded further (1) in that the statements appearing in its labeling, "Intrauterine Paste * * * Caution—To be used only by a physician with adequate and continuous supervision and employing modern surgical asepsis," and "For Induction of Labor * * * For Incomplete Miscarriage," were false and misleading since they represented and suggested that the article would be safe and appropriate for injection into the uterine cavity for purposes of inducing labor, terminating pregnancy, or removing retained portions of the products of conception, whereas the article, whether used by a physician with adequate and continued supervision and employing modern surgical asepsis or otherwise, would not be safe and appropriate for such purposes, but would be unsafe and dangerous and was capable of producing serious and even fatal consequences; and (2) in that the statements on the labeling, "For Dysmenorrhea * * * For Endometritis, Cervical and Uterine Discharges" were false and misleading since the article would not be an effective medicament for the treatment of dysmenorrhea, endometritis, or cervical or uterine discharges.

On September 11, 1943, the defendant entered a plea of guilty, and on November 2, 1943, the court imposed a fine of $200 and a sentence of 9 months in jail.

1102. Adulteration and misbranding of sodium citrate solution. U. S. v. 1,500 Boxes of Sodium Citrate Solution (and 7 other seizure actions against the same product). Decrees of condemnation and destruction. (F. D. C. Nos. 9182, 9184, 9232, 9265, 9310, 9311, 9385, 9388. Sample Nos. 3633–F, 5762–F, 10076–F, 16611–F, 29380–F, 29472–F, 34613–F, 37501–F, 41782–F.)

Between January 14 and February 23, 1943, the United States attorneys for the Western District of Texas, the Northern District of Georgia, the Eastern District of Virginia, the District of Kansas, the Eastern District of Missouri, the District of Colorado, the Southern District of Georgia, and the Northern District of Ohio filed libels against the following quantities of sodium citrate solution: 2,750 ampuls at Savannah, Ga.; 1,500 boxes at San Antonio, Tex.; 4,000 boxes at Atlanta, Ga.; 2,875 cartons at Richmond, Va.; 3,500 cartons at Kansas City, Kans.; 1,100 cartons at St. Louis, Mo.; 600 packages at Denver, Colo.; and 4,000 boxes at Toledo, Ohio, each box, carton, and package containing 6 ampuls. They alleged that the article, which had been consigned by the National Drug Co., had been shipped from Philadelphia, Pa., within the period from on or about November 12 to December 31, 1942; and charged that it was adulterated and misbranded. On February 27, 1943, an amended libel was filed against the lot at Toledo to correct the code reference of that lot. On March 18, 1943, the libel against the lot at Savannah was amended to cover the amount of 5,700 ampuls in lieu of 2,750 ampuls; and a portion of the lot at Savannah having been erroneously seized by the marshal, an order was entered providing for the return to the United States Army Medical Depot of 10,500 ampuls out of the total seizure of 16,200 ampuls.

The article was alleged to be adulterated in that it purported to be a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, as "Anticoagulant Solution of Sodium Citrate No. 3—Sterile Anticoagulant Solution of Sodium Citrate for Parenteral Use," but its quality and purity fell below the standard set forth in the Pharmacopoeia since it failed to meet the pyrogen test set forth therein.

It was alleged to be misbranded in that it was dangerous to health when used in the dosage prescribed, recommended, and suggested in the labeling thereof, "The contents of a 50 cc. ampul containing the 2½% solution, mixed with 450 cc. of blood produces a transfusion mixture"; and in that the statement in its labeling, "Ampul Sterile Solution Sodium Citrate, 2½% N. F. For use in transfusions to prevent the clotting of blood," was misleading since the article contained pyrogens and was not suitable for use in transfusions, and since the

National Formulary does not recognize the name "Ampul Sterile Solution Sodium Citrate, 2½%."

Between February 26 and April 26, 1943, no claim having been presented for the release of the product, judgments of condemnation were entered and it was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

1103. Misbranding of Formula No. 1520. U. S. v. 2 Cases of Formula No. 1520. Default decree of condemnation and destruction. (F. D. C. No. 10259. Sample No. 22782–F.)

On July 15, 1943, the United States attorney for the Eastern District of Pennsylvania filed a libel against 2 cases of Formula No. 1520 at Philadelphia, Pa., alleging that the article had been shipped on or about June 11, 1943, from New York, N. Y., by J. L. Hopkins and Company; and charging that it was misbranded.

The article consisted of a mixture of Epsom salt, sulfur, baking soda, and plant drugs including senna.

It was alleged to be misbranded (1) in that its label failed to bear the common or usual name of each active ingredient; (2) in that its label failed to bear adequate directions for use since no directions for use appeared on the label; (3) in that its label failed to bear adequate warnings against use since the article was a laxative and its label failed to warn that a laxative should not be taken in cases of nausea, vomiting, abdominal pain, or other symptoms of appendicitis; and (4) in that its label failed to bear adequate warnings against unsafe duration of administration since its label failed to warn that frequent or continued use of a laxative might result in dependence upon a laxative to move the bowels.

On August 30, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1104. Misbranding of mixed drugs. U. S. v. 4 Cartons of Mixed Drugs. Default decree of condemnation and destruction. (F. D. C. No. 10139. Sample No. 22779–F.)

On June 23, 1943, the United States attorney for the Eastern District of Pennsylvania filed a libel against an article consisting of 4 cartons containing 2 unlabeled packages (about 10 pounds each) of mixed drugs, 9 1-pound packages of powdered sugar, and miscellaneous labeling, at Philadelphia, Pa., alleging that the article had been shipped on or about June 9, 1943, from New York, N. Y., by Elsie Bleeker; and charging that it was misbranded. The cartons, some of which bore the name "Natura," others "Nu-Vita," all carried the statement: "Contents: Licorice, Sulphur, Cascara Sag., Senna, Bicarb. Soda, Magnesium Sulphate, USP, Sugar."

Examination of the unlabeled mixed drugs showed that they contained senna, Epsom salt (magnesium sulfate), sodium bicarbonate, and sulfur.

The article was alleged to be misbranded because of false and misleading statements appearing in its labeling which represented and suggested that it was an effective treatment for low or high blood pressure, rheumatism, backache, getting up nights, child bed-wetting, and swollen feet; that it was an "Herb Powder"; and that it was a product of either Mexico or America. It was alleged to be misbranded further (1) in that it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents; (2) in that its label failed to bear the common or usual name of each active ingredient of the preparation; (3) in that its labeling failed to bear adequate directions for use since the article was a laxative and the directions which appeared in the labeling provided for continuous administration, whereas a laxative should not be used continuously; and (4) in that its labeling failed to bear adequate warnings against unsafe duration of administration since its labeling failed to warn that frequent or continued use of a laxative might result in dependence upon a laxative to move the bowels.

On July 12, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1105. Misbranding of Dr. Sibbett's Improved Big Six and Original Big Six. U. S. v. 23½ Dozen Bottles and 3¾ Dozen Bottles of Dr. Sibbett's Improved Big Six, and 1¾ Dozen Bottles of Dr. Sibbett's Original Big Six. Default decree of condemnation and destruction. (F. D. C. No. 9985. Sample Nos. 37674–F, 37675–F.)

On May 21, 1943, the United States attorney for the Eastern District of Michigan filed a libel against 23½ dozen bottles, each containing 3 fluid ounces, and

3¾ dozen bottles, each containing 6 fluid ounces, of Dr. Sibbett's Improved Big Six; and 1¾ dozen bottles, each containing 6 fluid ounces, of Dr. Sibbett's Original Big Six at Detroit, Mich.; alleging that the articles had been shipped by the Sibbett Medicine Co., Cleveland, Ohio, on or about April 9, 1943; and charging that they were misbranded.

Examination disclosed that the articles were of the same compostion, consisting essentially of 227 grains of Epsom salt per fluid ounce, together with small amounts of ammonium chloride, caffeine citrate, tincture of ferric chloride, and oil of lemon in water.

The articles were alleged to be misbranded in that the statements appearing on their labels which represented and suggested that the articles would be effective in relieving colds and headaches; that they contained quinine sulfate and glycerin; and that they contained solution of iron (tincture of iron chloride), citric acid, caffeine citrate, and oil of lemon in amounts sufficient to constitute active ingredients, were false and misleading since the articles would not be effective in relieving colds and headaches, did not contain quinine sulfate and glycerin, and did not contain solution of iron, citric acid, caffeine citrate, and oil of lemon in amounts sufficient to constitute active ingredients. The articles were alleged to be misbranded further (1) in that the words, statements, and information required by the law to appear on the label or labeling were not prominently placed thereon with such conspicuousness as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use, since the required words, statements, and other information were obscured by a red figure 6 covering the main portion of the label, except the firm's name and address; and (2) in that the labeling failed to bear adequate directions for use, since the articles were laxatives and the directions which appeared in the labeling provided for continuous administration, whereas a laxative should not be used continuously.

On July 16, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS[3]

1106. Adulteration and misbranding of "Be" Bex, and misbranding of Hi-Test Pine Extract. U. S. v. Oxford Products, Inc., and Jerome H. Rose. Pleas of guilty. Fine of $300 and costs imposed against each defendant; sentence against corporate defendant suspended. (F. D. C. No. 9673. Sample Nos. 6725–F, 8706–F.)

On September 16, 1943, the United States attorney for the Northern District of Ohio filed an information against Oxford Products, Inc., Cleveland, Ohio, and Jerome H. Rose, president of the corporation, alleging shipment from the State of Ohio into the State of Iowa of a quantity of "Be" Bex, on or about December 23, 1942, and from the State of Ohio into the State of Missouri of a quantity of Hi-Test Pine Extract, on or about January 16, 1943.

Analysis of the "Be" Bex disclosed that it contained approximately 330 International Units of vitamin B_1 per fluid ounce. The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it was represented to possess, since it was represented to contain 660 International Units of vitamin B_1 per fluid ounce, whereas it contained less than that amount. It was alleged to be misbranded because of false and misleading statements on its label which represented and suggested that the article would aid in promoting the appetite and in protecting the body from nerve disorder resulting from vitamin deficiency; that it would be efficacious in the cure, mitigation, treatment, or prevention of retarded growth, constipation, migraine headaches, and nutritional anemia; and that it would be helpful in the promotion of greater vigor, better functional digestion, and wholesomeness of the skin. It was alleged to be misbranded further in that the statements on its label were misleading which represented and suggested that poor appetite, nerve disorder, retarded growth, constipation, migraine headaches, nutritional anemia, lack of vigor, poor digestion, and unwholesomeness of the skin were usually caused by lack of the vitamins contained in the article; and that the user might reasonably expect correction and alleviation of those conditions by the use of the article, whereas such conditions are not usually caused by lack of the vitamins contained in the article, but usually result from other causes, and the user might not

[3] See also No. 1102.

reasonably expect correction and alleviation of those conditions by use of the article as directed or otherwise, since it would not ordinarily be efficacious for such purposes. The article was also alleged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in the notices of judgment on foods.

Analysis of the Hi-Test Pine Extract disclosed that it had the odor of creosote, and contained not more than 1.49 minims of chloroform per fluid ounce and not more than 4.36 percent of alcohol by volume. The article was alleged to be misbranded in that the statements on its label, "22 Minims Chloroform per fld. oz.," and "Alcohol 17% Chloroform 22 Minims Per Fluid Ounce," were false and misleading; and in that the words "Pine Extract" were misleading, since they suggested that the article was composed solely of pine extract and derived its therapeutic properties solely from the pine extract, whereas the article contained therapeutically active ingredients other than pine extract, i. e., creosote and chloroform.

On October 25, 1943, the defendants entered pleas of guilty and the court sentenced the individual defendant to pay a fine of $50 on each of the first 4 counts relating to the "Be" Bex, and a fine of $100 on the fifth count relating to the Hi-Test Pine Extract, a total fine of $300 and costs. The same sentence was imposed against the corporate defendant, but this sentence was suspended.

1107. Adulteration and misbranding of carbon tetrachloride. U. S. v. National Package Drugs, Inc. Plea of guilty. Fine, $2,000. (F. D. C. No. 9643. Sample Nos. 29264–F, 29277–F, 37441–F.)

On June 19, 1943, the United States attorney for the Eastern District of Missouri filed an information against the National Package Drugs, Inc., St. Louis, Mo., alleging shipment on or about October 15 and December 22, 1942, from the State of Missouri into the States of Virginia and Georgia of quantities of carbon tetrachloride which was adulterated and misbranded.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which, carbon tetrachloride, was recognized in the United States Pharmacopoeia official at the time of shipment, but its quality or purity fell below the standard set forth in that compendium since, in the case of the Georgia lot, the weight of the residue from the evaporation of 50 cc. exceeded 0.001 gram, the maximum permitted by the Pharmacopoeia, and the amount of the free chlorine and carbonizable substances exceeded the maximum permitted; and, in the case of the Virginia lot, the article was not odorless but had an odor resembling paint, and it contained carbonizable substances in excess of the amount permitted; and the difference in quality and purity from the standard was not stated plainly upon the label.

Both lots were alleged to be misbranded in that the statement, "Carbon Tetrachloride U. S. P.," borne on the label of the article, was false and misleading.

On October 26, 1943, the defendant having entered a plea of guilty, the court imposed a fine of $500 upon each of 4 counts, a total fine of $2,000.

1108. Adulteration and misbranding of tincture of nux vomica. U. S. v. Kremers-Urban Co. Plea of nolo contendere. Fine, $100. (F. D. C. No. 9656. Sample No. 38025–F.)

On June 16, 1943, the United States attorney for the Eastern District of Wisconsin filed an information against the Kremers-Urban Co., a corporation, Milwaukee, Wis., alleging shipment on or about January 14, 1943, from the State of Wisconsin into the State of Illinois of a quantity of the above-named product.

The article was alleged to be adulterated in that it purported to be and was represented as tincture of nux vomica, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from the standard set forth therein since the Pharmacopoeia provides that tincture of nux vomica shall yield from each 100 cc. not more than 0.125 gram of strychnine, whereas the article yielded not less than 0.144 gram of strychnine per 100 cc., and its difference in strength from the standard set forth in the compendium was not plainly stated on the label.

The article was alleged to be misbranded in that the statements, "Tincture Nux Vomica U. S. P. Each 100 cc. contains 0.115 Gm. Strychnine," borne on its label, were false and misleading.

On January 6, 1944, the defendant having entered a plea of nolo contendere, the court imposed a fine of $50 on each of 2 counts.

1109. Adulteration and misbranding of oil of cinnamon. U. S. v. 4 Cans of Oil of Cinnamon (and 3 other seizure actions against oil of cinnamon). Decrees of condemnation. Portions of product ordered delivered to the Food and Drug Administration and to local hospitals; remainder ordered sold. (F. D. C. Nos. 10440, 10742, 10929, 11015. Sample Nos. 23434–F, 23662–F to 23664–F, incl., 23830–F, 47543–F, 48468–F.)

Between August 19 and October 27, 1943, the United States attorneys for the District of New Jersey, the Southern District of Ohio, and the Eastern District of Missouri filed libels against 4 cans and 9 tins at Bridgeton, N. J., 4 cans at Cincinnati, Ohio, and 4 cans at St. Louis, Mo., each can or tin containing 25 pounds of oil of cinnamon, alleging that the articles, which had been consigned from New York, N. Y., from on or about May 4 to July 1, 1943, had been shipped by Magnus, Mabee & Reynard, Inc.; and charging that it was adulterated and misbranded. The article was labeled in part: "Purity * * * Oil Cinnamon—U. S. P. (Oil Cassia Redistilled USPX)."

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth therein since the article was not the volatile oil distilled from the leaves and twigs of Cinnamomum Cassia rectified by distillation; and in that material other than the oil so distilled and rectified had been substituted in whole or in part for the product.

It was alleged to be misbranded in that the statement in its labeling, "Oil Cinnamon—U. S. P.," was false and misleading as applied to an article that was not Oil of Cinnamon—U. S. P.

Between October 29 and December 24, 1943, no claimant having appeared, judgments of condemnation were entered. The New Jersey lots were ordered sold for industrial purposes, with the exception of certain portions which were ordered delivered to the Food and Drug Administration. The Ohio lot was ordered delivered to local hospitals, and the Missouri lot was ordered sold.

1110. Adulteration and misbranding of gum arabic and antimony potassium tartrate. U. S. v. 44 Bottles of Gum Arabic and 20 Bottles of Antimony Potassium Tartrate (and 1 other seizure action against antimony potassium tartrate). Default decrees of condemnation and destruction. (F. D. C. Nos. 11111, 11170. Sample Nos. 38825–F, 52922–F, 52923–F.)

On November 13 and 29, 1943, the United States attorneys for the District of Maryland and the Northern District of Illinois filed libels against 44 bottles of gum arabic and 20 bottles of antimony potassium tartrate at Perry Point, Md., and against 22 bottles of the latter product at Hines, Ill., alleging that the articles had been shipped on or about August 17 and 18, 1943, by the City Chemical Corporation, from New York, N. Y., and Jersey City, N. J.; and charging that they were adulterated and misbranded.

The gum arabic was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth therein since the Pharmacopoeia defines gum arabic (acacia) as the dried, gummy exudation from the stems and branches of certain species of acacia, and provides that the product shall yield not more than 1 percent of water-insoluble residue and the color shall be white to yellowish white, whereas the article contained a material amount of plant fragments, the water-insoluble residue was more than 1 percent, and many pieces of the acacia were of a dark brown color. It was alleged to be misbranded in that the statement "Gum Arabic U. S. P.–XII (Acacia)," appearing on the label, was false and misleading.

The antimony potassium tartrate was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth therein since the Pharmacopoeia provides that 0.1 gram of antimony and potassium tartrate shall contain not more than 0.02 milligram of arsenic trioxide, whereas the article contained approximately 10 times the amount of arsenic trioxide permitted by the compendium. It was alleged to be misbranded in that the statement "Antimony Potassium Tartrate U. S. P.–XII," appearing on its label, was false and misleading.

On December 20, 1943, and January 13, 1944, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

1111. Adulteration and misbranding of terpin hydrate. U. S. v. 59 Bottles of Terpin Hydrate. Default decree of condemnation and destruction. (F. D. C. No. 10136. Sample No. 759–F.)

Examination showed that the article had a strong turpentine-like odor, whereas the United States Pharmacopoeia provides that "Terpin Hydrate has no odor of turpentine."

On June 28, 1943, the United States attorney for the Northern District of Illinois filed a libel against 59 bottles of terpin hydrate at Hines, Ill., alleging that the article had been shipped on April 28, 1943, from New York, N. Y., by the B. L. Lemke Co.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that it purported to be a drug the name of which is recognized in an official compendium, but its quality fell below the standard set forth therein.

It was alleged to be misbranded in that the statement on the bottle label, "Terpin Hydrate U. S. P. XII," was false and misleading since the article did not comply with the specifications of the United States Pharmacopoeia.

On September 17, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1112. Adulteration of cascara bark. U. S. v. 161 Bags, Labeled in Part "Cascara Sagrada U. S. P." Decree of condemnation. Product ordered released under bond to be brought into compliance with the law. (F. D. C. No. 10277. Sample No. 11818–F.)

On July 17, 1943, the United States attorney for the Northern District of California filed a libel against 161 bags of cascara bark at Oakland, Calif., alleging that the article had been shipped on or about May 31, 1943, from Portland, Oreg., by S. B. Penick; and charging that it was adulterated.

Examination disclosed that the article consisted of damp, moldy, mildewed, and discolored cascara bark.

It was alleged to be adulterated in that it purported to be and was represented as a drug, cascara sagrada, the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth therein since it was not free from moldiness and showed substantial discoloration and deterioration.

On August 9, 1943, S. B. Penick & Co., Portland, Oreg., having appeared as claimant, judgment of condemnation was entered and the product was ordered released under bond to be brought into compliance with the law under the supervision of the Food and Drug Administration.

1113. Adulteration of sodium citrate and sodium chloride solutions. U. S. v. 14 Cases of Sodium Citrate Solution (and 10 other seizure actions against the above-named products). Default decrees of condemnation and destruction. (F. D. C. Nos. 9397, 9399, 9400, 9431, 9432, 9543, 9706, 10731, 11523, 11524, 11705, 11748. Sample Nos. 12050–F, 12073–F, 15940–F, 16124–F, 16125–F, 30856–F, 30858–F, 30859–F, 36483–F to 36487–F, incl., 42486–F, 54509–F to 54511–F, incl., 57130–F, 61085–F to 61087–F, incl.)

These products purported to be "Anticoagulant Solution of Sodium Citrate" and "Isotonic Solution of Sodium Chloride," respectively, names recognized in the United States Pharmocopoeia. The Pharmacopoeia provides that, unless otherwise specified, sterile products for parenteral use must be dispensed; and that they must conform with the requirements for injections. These requirements are, among others, that injections which are solutions of soluble medicaments must be clear, and free of any turbidity or undissolved material which can be detected readily when examined in accordance with the method described therein. The products when so examined were found to be not clear and free from turbidity.

Between February 26, 1943, and February 9, 1944, the United States attorneys for the District of Colorado, the Western District of Washington, the District of Oregon, the District of Utah, the Northern District of Illinois, the Southern District of New York, and the Western District of Texas filed libels against 1 case containing 5 flasks, and 10 cases, each containing 6 flasks, at Portland, Oreg., and 49 cases, each containing 6 bottles, at New York, N. Y., of sodium chloride solutions, and against the following quantities of sodium citrate solutions: 22 cases, each containing 6 flasks, and 355 bottles at Denver, Colo.; 79 cases and 156 cartons, each containing 6 flasks, at Seattle, Wash.; 17 cases, each containing 6 flasks, at Portland, Oreg.; 54 flasks at Salt Lake City, Utah; 840 cases, each containing 6 bottles, at Chicago, Ill.; and 258 bottles at San Antonio, Tex. They alleged that the articles, which had been consigned by Cutter Laboratories, had been shipped in interstate commerce within the period from

on or about January 5, 1942, to December 2, 1943, from Berkeley and Oakland, Calif., Chicago, Ill., and Seattle, Wash.; and charged that they were adulterated.

Various lots of the articles were labeled in part: "Saftivac [or "Saftifuge"] * * * Sodium Citrate * * * In Isotonic [or "Physiological"] Solution of Sodium Chloride," "Physiological Solution of Sodium Chloride," "Saftiflask Physiological Solution of Sodium Chloride (Normal Salt Solution)," or "Sediflask * * * Sodium Citrate * * * in Isotonic Solution of Sodium Chloride."

The articles were alleged to be adulterated in that they purported to be drugs the names of which are recognized in the United States Pharmacopoeia, an official compendium, but their quality and purity fell below the standard set forth therein since they were not free from undissolved material.

Between April 6, 1943, and April 7, 1944, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

1114. Adulteration and misbranding of gauze bandage. U. S. v. 34 Dozen packages of Gauze Bandage. Default decree of condemnation. Product ordered delivered to a local hospital. (F. D. C. No. 10250. Sample No. 32677–F.)

Examination disclosed that this product was not sterile but was contaminated with living micro-organisms, whereas the United States Pharmacopoeia provides that gauze bandage must be sterile.

On July 15, 1943, the United States attorney for the Southern District of Indiana filed a libel against 34 dozen packages of gauze bandage at Indianapolis, Ind., alleging that the article had been shipped on or about June 10, 1943, by Forest City Products, Inc., Cleveland, Ohio; and charging that it was adulterated and misbranded. The article was labeled in part: "Sentinel Gauze Bandage Sterilized After Packaging 2 In. x 6 Yds."

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in an official compendium, but its quality and purity fell below the standard set forth therein.

It was alleged to be misbranded in that the label, containing the words "gauze bandage," was false and misleading when applied to the article, which was not sterile.

On September 3, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed. On September 9, 1943, an amended decree was entered, ordering that the product be delivered to a local hospital, conditioned that it be properly sterilized before use.

1115. Adulteration and misbranding of absorbent cotton and gauze bandages. U. S. v. 324 Packages, 1,212 Packages, and 3,800 Pounds of Absorbent Cotton, and 1,970 Dozen Packages of Gauze Bandages. Decrees of condemnation. Portions of products ordered released under bond; other portions ordered to be disposed of by sale, destruction, and delivery to the Red Cross. (F. D. C. Nos. 8878, 8909, 9050, 9229, 9244. Sample Nos. 10075–F, 14934–F, 14935–F, 29246–F, 31368–F, 32202–F.)

Between November 16, 1942, and January 25, 1943, the United States attorneys for the Northern District of Georgia, the Northern and Southern Districts of Ohio, the Southern District of California, and the Western District of Texas filed libels against 324 and 1,212 1-ounce packages of absorbent cotton at Toledo, Ohio, and Atlanta, Ga., respectively, 3,800 pounds of absorbent cotton at Columbus, Ohio, 120 dozen packages of 2-inch size and 150 dozen packages of 3-inch size gauze bandages at Los Angeles, Calif., and 1,700 dozen packages of 4-inch size gauze bandages at San Antonio, Tex., alleging that the articles, which had been consigned by the Seamless Rubber Co., had been shipped from St. Louis and Valley Park, Mo., within the period from on or about October 6 to December 15, 1942; and charging that the gauze bandages at Los Angeles were misbranded, and that the gauze bandages at San Antonio and all lots of the absorbent cotton were both adulterated and misbranded. The cotton was labeled in part: "Swansdown Absorbent Cotton."

Examination disclosed that the articles, which were represented to be sterile, were not sterile but were contaminated with viable micro-organisms.

The absorbent cotton at Columbus was alleged to be adulterated in that its purity and quality fell below that which it purported or was represented to possess. The other lots of absorbent cotton and the gauze bandages at San Antonio were alleged to be adulterated in that they purported to be drugs the names of which are recognized in the United States Pharmacopoeia, an official compendium, but their quality and purity fell below the standard set forth therein since they were not sterile.

The absorbent cotton was alleged to be misbranded in that the statements appearing in the labeling of the Atlanta lot, "U. S. P. Standard Sterilized," and in the labeling of the other lots, "Absorbent Cotton U. S. P. Standard Sterilized," were false and misleading.

The gauze bandages were alleged to be misbranded in that the statements appearing in the labeling of the lot at San Antonio, "Sterilized * * * The bandage in this package was sterilized during manufacture and sterilized again after packaging. * * * Esterilizada," and substantially similar statements in the labeling of the lot at Los Angeles, were false and misleading.

On March 31 and August 4, 1943, the Seamless Rubber Co. having appeared as claimant for the Columbus and San Antonio lots, judgments of condemnation were entered and the products were ordered released under bond to be brought into compliance with the law. Between January 19 and February 27, 1943, no claimant having apeared for the other lots, judgments of condemnation were entered and it was ordered that the Atlanta lot be sterilized and sold; that the Los Angeles lot be delivered to a local chapter of the Red Cross; and that the Toledo lot be destroyed.

1116. Defective prophylactics. U. S. v. 900 Gross of Rubber Prophylactics. Default decree of condemnation and destruction. (F. D. C. No. 10279. Sample No. 45459–F.)

On July 19, 1943, the United States attorney for the Southern District of New York filed a libel against 900 gross of rubber prophylactics at New York, N. Y., alleging that the article had been shipped on or about June 3 and 10, 1943, from East Newark, N. J., by the Ardell Razor Blade Co.; that the article was defective in that it contained holes; and that it was subject to seizure and condemnation. The article was labeled in part: "Silver-Town," or "Clipper Made from Liquid Latex."

On August 11, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1117. Adulteration of prophylactics. U. S. v. 50 Gross and 50 Gross of Rubber Prophylactics. Default decrees of condemnation and destruction. (F. D. C. Nos. 10311, 10327. Sample Nos. 1757–F, 1759–F.)

On July 27 and 30, 1943, the United States attorney for the Northern District of Illinois filed libels against 100 gross of prophylactics at Chicago, Ill., alleging that the article had been shipped by Trutex Products, Inc., from Cleveland, Ohio, on July 13 and 14, 1943; and charging that it was adulterated.

Examination of samples disclosed that between 9 and 22 percent were defective in that they contained holes.

The article was alleged to be adulterated in that its quality fell below that which it purported or was represented to possess.

On September 16 and 17, 1943, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS[4]

DRUGS FOR HUMAN USE

1118. Misbranding of Via-Min. U. S. v. Albert Hassman (Universal Products Co.). Plea of guilty. Fine, $500 and costs. (F. D. C. No. 8789. Sample Nos. 90166–E, 90167–E.)

On March 20, 1943, the United States attorney for the Northern District of Ohio filed an information against Albert Hassman, trading as the Universal Products Co., Cleveland, Ohio, alleging that on or about March 7 and 9, 1942, the defendant shipped to his agents or demonstrators at Boston, Mass., certain quantities of Via-Min; that on or about March 4, 1942, the defendant shipped a number of printed circulars; that the printed circulars had been prepared by the defendant for the purpose of furthering the sale of Via-Min; and that, while the shipment of March 7, 1942, was held for sale after shipment in interstate commerce, the defendant caused the agents and demonstrators to place the circulars together with and displayed with such shipment, as a result of which they became associated with and accompanied the article.

Analysis showed that the article was a clear, light brown liquid consisting of water with dissolved mineral constituents.

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[4] See also Nos. 1101, 1102, 1104–1111, 1114, 1115.

Misbranding was alleged in that the statements appearing on the labels of the bottles containing the article, "Ingredients: Grains per gallon. Specific Gravity 1.049; Ferric Sulphate 1752; Aluminum Sulphate 29; Calcium Sulphate 79; Magnesium Sulphate 409; Sodium Phosphate 70 * * * Total Solids 4,413," were false and misleading since the specific gravity of the article varied between 1.018 and 1.027, and the article contained per gallon not less than 955 grains of aluminum sulfate and not more than 1,682 grains of ferric sulfate, 25 grains of calcium sulfate, 193 grains of magnesium sulfate, and 2,239 grains of total solids, and, in one portion, not more than 17 grains of sodium phosphate. It was alleged to be misbranded further in that the statement "used on minor Sores and Cuts," borne on the bottle label, was false and misleading, since that statement represented and suggested that the article would be efficacious in the treatment of minor sores and cuts, whereas it would not be so efficacious.

It was also alleged, with respect to the shipment of March 7, 1942, that the lot, when accompanied by the circulars, was further misbranded because of false and misleading statements in the circular which represented and suggested that the article would be efficacious in the cure, mitigation, treatment, or prevention of acidosis, acne, eczema, muddy skin, pimples, anemia, malnutrition, underweight, arthritis, rheumatism, gout, asthma, auto-intoxication, biliousness, high blood pressure, boils, Bright's disease, bronchitis, colds, sinus trouble, catarrh, constipation, diabetes, failing eyesight, cataract, falling hair, thin, hard, brittle finger nails, gall bladder disorders, gallstones, jaundice, goiter, hardening of the arteries, hay fever, stiffness of the joints, leucorrhea, low vitality, lack of endurance, lack of pep, nervousness, sciatic rheumatism, neuralgia, neuritis, nerve exhaustion, obesity, enlarged prostate gland, poor circulation, sexual indifference, tooth decay, spongy gums that bleed easily, tuberculosis of the lungs, and undernourishment of children; that the article would build and maintain the bones, teeth, and tendons, counteract acidity, heal wounds, and aid vitality and endurance; that it would be efficacious in the cure, mitigation, treatment, or prevention of tuberculosis, rickets, pyorrhea, heart disease, painful menstruation, excessive bleeding and hemorrhages, anemia, asthma, circulatory diseases, female disorders, nerve exhaustion, and indigestion; that it would be efficacious in building and nourishing the brain, nerves, and bones, and aid in strengthening the mental power; that it would counteract acidosis, purify the blood by eliminating carbon dioxide, and dissolve hard deposits in the joints; that it would be efficacious in the treatment of halitosis and to purify the system; that it would aid in keeping the hair, skin, and sex organs in a healthy condition, and would intensify the emotions; that it would be efficacious as a nerve sedative; that it would vitalize the lungs, neutralize acid waste materials, and supply energy and vitality; that it would be efficacious in producing glossy hair, hard teeth, keen hearing, and sparkling eyes; and that it would aid greatly in recovery from disease or injury.

On October 1, 1943, the defendant entered a plea of guilty and was fined $500 and assessed costs in the amount of $28.31.

1119. Misbranding of Dwarfies Wheatmix and wheat germ. U. S. v. Dwarfies Corporation. Plea of guilty. Fine, $225 and costs. (F. D. C. No. 10553. Sample Nos. 3130–F, 3226–F, 3227–F.)

On December 30, 1943, the United States attorney for the Southern District of Iowa filed an information against the Dwarfies Corporation, Council Bluffs, Iowa, alleging shipment on or about September 30, 1942, and January 29, 1943, from the State of Iowa into the State of Nebraska of quantities of Wheatmix and wheat germ which were misbranded. The articles were labeled in part: "Dwarfies Wheatmix," or "Dwarfies Toasted Wheat Germ."

The Wheatmix was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that it would make the consumer healthy and energetic and would maintain body health and energy; that it would give the consumer sound nerves and a good appetite; that it would insure proper growth and elimination; and that it would be efficacious in the cure, mitigation, treatment, or prevention of minor ailments and serious sickness, were false and misleading since the article would not be efficacious for the purposes recommended or accomplish the results claimed.

The wheat germ was alleged to be misbranded because of false and misleading statements appearing in its labeling which represented and suggested that it would be efficacious in the cure, mitigation, treatment, or prevention of nerve and digestive ailments; that it would be efficacious to improve morale; that it would make the user regular and improve his disposition; that it would be efficacious in the prevention or treatment of pellagra and vitamin deficiency

diseases, and in the treatment of lowered vitality, headache, nervousness, irritability, eye trouble, and retarded growth; that it would stimulate the appetite and improve the digestion of carbohydrates and fats; that it would prevent abnormal changes in the eyes and failing vision; that it would be of value for prospective or nursing mothers; and that it would give the user zest and body vigor and be efficacious in building red blood cells and replacing worn-out cells. The article would not be efficacious for the purposes recommended or accomplish the results claimed.

The articles were also alleged to be misbranded under the provisions of the law applicable to foods, as reported in the notices of judgment on foods.

On January 25, 1944, the defendant having entered a plea of guilty, the court imposed a total fine of $225 and costs, the fine on the counts charging violation of the drug sections of the Act amounting to $75.

1120. Misbranding of Einik's Red Ointment and Einik's Root. U. S. v. Zenon Anthony Einik (Z. A. Einik Ointment Co.). Plea of guilty. Fine, $20. (F. D. C. No. 9691. Sample Nos. 22552–F, 22553–F.)

On September 21, 1943, the United States attorney for the District of Connecticut filed an information against Zenon Anthony Einik, trading as the Z. A. Einik Ointment Co., Union City, Conn., alleging shipment on or about September 9, 1942, from the State of Connecticut into the State of Pennsylvania of quantities of the above-named products which were misbranded.

Analysis of the Red Ointment disclosed that it consisted of a mixture of creosote, capsicum, peppermint oil, and methyl salicylate in a base probably chiefly petrolatum.

The article was alleged to be misbranded because of false and misleading statements in its labeling which represented and suggested that the article would be efficacious in the treatment of rheumatic and neuralgic pains and aches; that it would relieve local congestion and throat irritation; that it would be efficacious in the treatment of mild cases of lumbago, colds in the chest, aches and rheumatic pains in the back and joints, colds, catarrh, rheumatism, pain in the back, stitch in the sides, severe pains in the chest and joints, and tonsilitis; that 1 hour after application pain would stop; that the article would be efficacious in the treatment of kidney pains and rheumatic pains due to dampness and colds, and in the treatment of headache, coughs, or distresses of the chest due to cold and local congestion, sore throat, aches in the hands and feet, and soreness of the gums and teeth; that it would be an appeasing medium for all ailments; that it would facilitate the circulation of the blood to various parts of the body; that its use would preserve health; that it was an efficacious treatment for catarrh of the nose, and headaches due to cold, and cold during female periods; that it would reawaken the circulation, thus causing pains to disappear almost immediately; that it would be efficacious in the treatment of bronchitis, croup, asthma, aches and pains due to accident and low vitality, sprains in the joints and muscles, pleurisy, and frosted hands and feet; that it would be a protection against pneumonia and pains in general, and would provide relief and a speedy cure for rheumatism, lumbago, sore throat, pain in the chest, shoulders and throat, neuralgia, pains of any kind in the back, and sprains in the joints and muscles; and that it possessed the curative properties indicated by the expression on the display carton: "A Friend of Suffering Humanity." It was alleged to be misbranded further in that it was in package form and did not bear a label containing an accurate statement of the quantity of the contents, since the label on the boxes containing the article bore the statement "Net Wt. 1 Oz.," whereas the boxes contained less than 1 ounce net.

Analysis of Einik's Root disclosed that it was granulated Canadian stone root of usual appearance. It was alleged to be misbranded because of false and misleading statements in its labeling which represented and suggested that the article would be efficacious as a tonic and stimulant for simple debility or asthenia; that it would help tone up the system and aid in the better flow of digestive juices; that it would be efficacious against weakening of the system and energy; that it would be efficacious in the treatment of catarrh of the chest and weakening of the bladder from overwork; and that it would be efficacious as a solvent for the blood and as a treatment for rheumatism.

On September 27, 1943, the defendant entered a plea of guilty and the court imposed a fine of $10 on each count, a total of $20.

1121. Misbranding of Trapper's Preparation for Sinus. U. S. v. Cecil James Cardwell (Trapper's Remedies, Inc.). Plea of guilty. Fine, $10. (F. D. C. No. 8738. Sample No. 85673–E.)

On February 1, 1943, the United States attorney for the District of Idaho filed an information against Cecil James Cardwell, trading as Trapper's Remedies, Inc., Weiser, Idaho, alleging shipment on or about April 15, 1942, from the State of Idaho into the State of Washington of a quantity of the above-named product.

Analysis disclosed that the article consisted essentially of ground, woody material not classified as to specific identity.

The article was alleged to be misbranded because of false and misleading statements in its labeling which represented and suggested that the article would be efficacious in the cure, mitigation, treatment, or prevention of sinus disease, hay fever, nasal discharges, nasal catarrh, headache, colds, sore throat, coughs, influenza, trench mouth, and other diseases of the mouth, acid stomach, ulcers of the stomach, colitis, pain and vomiting, indigestion, and dyspepsia; that it would be efficacious to increase body weight, improve the circulation, bring color to the face, and improve the appetite and disposition, overcome nervousness, and make one less irritable and grouchy; and that it would be efficacious in the treatment of toothache, pinworms, mashed fingers, or burns, and would rid the blood stream of disease germs and build up resistance.

On September 22, 1943, the defendant entered a plea of guilty, and the court imposed a fine of $10.

1122. Misbranding of Ademo Tablets. U. S. v. 70 Dozen Bottles of Ademo Tablets (and 1 other seizure action against the same product). Decrees of condemnation. Portion of product ordered destroyed and remainder ordered released under bond for relabeling. (F. D. C. Nos. 10221, 11785. Sample Nos. 31063–F, 76304–F.)

On July 14, 1943, and February 15, 1944, the United States attorneys for the Western District of Washington and the Southern District of New York filed libels against the following quantities of Ademo Tablets which were packed in 42-tablet, 150-tablet, and 300-tablet bottles: 70 dozen bottles at Seattle, Wash., and 361 5/6-dozen bottles at New York, N. Y.; alleging that the article had been shipped from on or about March 2 to June 8, 1943, by the Ademo Corporation of America, Los Angeles, Calif.; and charging that it was misbranded. The article was labeled in part: "Formulated from the Active Principle of Violet Ray Treated (Red Blood Cell Building) fraction of Desiccated, Raw Liver Extractive, Iron, Special Type Yeast, Concentrated Hemoglobin (Blood Powder), Milk Whey, Chlorophyll, Plus the following for each 6 tablets: H. P. Thiamin (B–1) . . . 1200 I. U. H. P. Riboflavin (B–2) . . . 3000 Micrograms Niacin . . . 10,000 Micrograms Iron . . . 20.24 Milligrams. Also minerals containing trace elements of Calcium, Chlorine, Magnesium, Sulphur, Potassium, Phosphorus and Pantothenic Acid as Naturally found in Yeast and Liver."

Examination and assays disclosed that the article was essentially of the composition stated on its label.

The New York lot was alleged to be misbranded in that the following statements on its label and on the display card accompanying the article: "Don't Let 'Blood Deficiency' Keep You Rundown . . . Always Tired . . . Half Alive! Amazing New 3 Way Method Helps Build Rugged Red Blood! * * * [Picture of man and woman in vibrant health] Don't Ration Yourself on Blood—if you want Strength, Energy, Vibrant Health!" were false and misleading since the article would not build rugged red blood, or insure strength, energy, and vibrant health.

The article in the Washington lot was alleged to be misbranded because of false and misleading statements on the labels on display cartons entitled "Amazing New 3 Way Method Helps Build Rugged Red Blood!" and in circulars entitled "Now More Than Ever You Need Powerful Rugged Red Blood!" which accompanied the article, and which represented and suggested that it would build rugged red blood, insure strength, energy, vibrant health, and prevent and correct nutritional anemia, weak blood, lustreless eyes and colorless cheeks, tiredness, rapid heart beat, infections, muscular weakness, neuritis, sluggishness, nerve disease, loss of vitality, beriberi, brittle nails, dry, scaly skin, depression, loss of body weight, intestinal disorders, improper lactation, pellagra, malnutrition, irritability, digestive disorders, diarrhea, gingivitis, mental strain, nervousness, loss of gloss to the hair, premature aging, dermatitis (skin disease), partial deafness, fissures around the corners of the mouth, and unnaturally red lips and tongue.

Both lots were also alleged to be misbranded under the provisions of the law applicable to foods, as reported in the notices of judgment on foods.

On November 8, 1943, no claimant having appeared for the product in the Washington lot, judgment of condemnation was entered and the product, including all display cartons and circulars, was ordered destroyed. On May 22, 1944, Balanced Foods, Inc., New York, N. Y., claimant, having admitted the allegations of the libel against the New York lot, judgment of condemnation was entered and the product in that lot was ordered released under bond for relabeling under the supervision of the Federal Security Agency.

1123. Misbranding of vitamin tablets. U. S. v. 102 Bottles of Curley Cal-Pans Vitamins and 102 Bottles of Curley Bu-T-Caps Vitamins. Default decree of condemnation and destruction. (F. D. C. No. 10013. Sample Nos. 20488-F, 20489-F.)

On May 27, 1943, the United States attorney for the District of Massachusetts filed a libel against 102 bottles of Curley Cal-Pans Vitamins and 102 bottles of Curley Bu-T-Caps Vitamins, each bottle containing 30 tablets, at Boston, Mass., alleging that the articles had been shipped on or about April 21, 1943, from Philadelphia, Pa., by the Curley Distributing Co.; and charging that they were misbranded. The articles were labeled in part: (Cal-Pans) "Calcium Pantothenate 10 Mgm. each"; (Bu-T-Caps) "Vitamin A . . . 5,000 USP Units Vitamin D (Viosterol) . . . 1,000 USP Units Vitamin C (Ascorbic Acid) . . . 500 USP Units Vitamin B_1 (Thiamin Chloride) . . . 500 USP Units Vitamin B_2 (Riboflavin) . . . 1,000 Gamma Vitamin B_6 (Pyridoxine) . . . 200 Gamma Calcium Pantothenate . . . 1,000 Gamma Nicotinic Acid . . . 20 Mgm."

The Cal-Pans Vitamins were alleged to be misbranded in that certain statements appearing on a display card entitled "Does Gray Hair Worry You?" and in circulars entitled "VITAMINS The Way to Health and Beauty," and "Big Profits for Beauty Shops," were false and misleading since they represented and suggested that the article was effective in preventing the graying of hair or in restoring the natural color to gray hair, whereas it was not so effective.

The Bu-T-Caps Vitamins were alleged to be misbranded because of false and misleading statements appearing on the display card and in the circulars, which represented and suggested that the article was effective in insuring good health, beauty, and good complexion, or in preventing and correcting such disease conditions or abnormalities as poor teeth, retardation of growth, skin lesions, dry and wrinkled skin, brittle nails, lifeless hair, loss of appetite, liver and kidney ailments, susceptibility to infections, boils, abscesses, night blindness, body malformation, fatigue, loss of appetite, alimentary tract disfunctions and resultant anemia, neuritis, alcoholic neuritis, beriberi and pellagra, irritability and nervousness, palpitation and enlarged heart, murmurs, difficult breathing, malnutrition, retarded convalescence, fragile bones, anemia, scurvy, and rickets.

The articles were also alleged to be misbranded under the provisions of the law applicable to foods, as reported in the notices of judgment on foods.

On July 26, 1943, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

1124. Misbranding of DPS Formulae. U. S. v. 11 Bottles of DPS Formula 52, 16 Bottles of DPS Formula 57, 12 Bottles of DPS Formula 58, 11 Bottles of DPS Formula 61, 9 Packages of DPS Formula 66, 7 Bottles of DPS Formula 81, 25 Bottles of DPS Formula 100, 4 Bottles of DPS Formula 103, and 3 Bottles of DPS Formula 105. Default decree of condemnation and destruction. (F. D. C. No. 10098. Sample Nos. 15357-F to 15360-F, incl., 36122-F to 36126-F, incl.)

On June 25, 1943, the United States attorney for the District of Colorado filed a libel against the above-mentioned quantities of DPS Formulae at Denver, Colo., alleging that the articles had been shipped from the Dartell Laboratories, Los Angeles, Calif., from on or about March 23 to May 8, 1943; and charging that they were misbranded.

The DPS Formula 52 was labeled in part: "Ingredients: Fish Liver Oil concentrate, Soya oil containing lecithin, Wheat germ oil, mixed natural tocopherols, treated linseed oil containing the fatty unsaturates, principally linoleic and linolenic acids * * * Each perle contains not less than Vitamin A . . . 5000 U. S. P. Units. Vitamin E (a-tocopherol activity) 5000 Gammas with 200 Mg. free fatty acids of linseed oil (flaxseed oil) principally linoleic the linolenic acids." It was alleged to be misbranded in that the name "DPS

Formula 52" was a false and misleading device which represented and suggested that the article was efficacious for the following conditions: Impotency, sexual apathy, menopause, loss of muscular tone, anterior pituitary deficiency, and tendency to abort. It was alleged to be misbranded further in that the statement on its label, "Each perle contains not less than * * * With 200 Mg. free fatty acids of linseed oil (flaxseed oil) principally linoleic and linolenic acids," was misleading since the statement created the impression that the free fatty acids of linseed oil consisting principally of linoleic and linolenic acids in the amount of 200 milligrams were of appreciable nutritional and therapeutic significance when the article was consumed in accordance with the directions on the labels, whereas such acids when so consumed had no appreciable nutritional or therapeutic significance.

The DPS Formula 57 was labeled in part: "Ingredients: Fish liver oil concentrate, dehydrated garlic and alfalfa, lac-sulphur, and chlorophyll * * * Four tablets provide 2000 I. U. of Vitamin A, * * * 14 grains of dehydrated Garlic, 4 grains of Sulphur; and 2000 gammas of Chlorophyll." It was alleged to be misbranded in that the name "DPS Formula 57" was a false and misleading device which represented and suggested that the article was efficacious for the following conditions: Hypertension, toxic conditions, and bowel putrefaction.

The DPS Formula 58 was labeled in part: "Ingredients: Powdered kelp, dicalcium phosphate, fish liver oil concentrate, yeast, rice polishings, wheat germ * * * One tablet before each meal and upon retiring provides: Iodine . . . 0.7 Mg. Phosphorus . . . 144 Mg. Calcium . . . 176 Mg. Vitamin A . . . 1000 U. S. P. Units." It was alleged to be misbranded in that the name "DPS Formula 58" was a false and misleading device which represented and suggested that the article was efficacious in the following conditions: Lowered fat and protein metabolism, low basal metabolic rate, thyroid deficiency, low calcium metabolism, pregnancy and lactation, nervous disorders, obesity, and skin conditions.

The DPS Formula 61 was labeled in part: "Ingredients: Mixed natural tocopherols and wheat germ oil * * * Each perle contains not less than 5000 Gamma Vitamin E (a-tocopherol activity)." It was alleged to be misbranded in that the name "DPS Formula 61" was a false and misleading device which represented and suggested that the article was efficacious for the following conditions: Sterility, tendency to miscarriage, mental dullness, muscular weakness, skin lassitude, weakness of female organs, lack of motility of eye lens, paralysis, and anterior pituitary deficiency.

The DPS Formula 66 was labeled in part: "Contains the unsaturated fatty oils naturally present in wheat germ oil and fish liver oil concentrate. Special High Potency Vitamin A. Each capsule contains not less than 50,000 U. S. P. units Vitamin A from fish liver oil concentrate in wheat germ oil." It was alleged to be misbranded in that the name "DPS Formula 66" was a false and misleading device which represented and suggested that the article was efficacious for the following conditions; Sinusitis, catarrh, asthma, colds, otitis media, infections involving the mucosae, and eye disorders.

The DPS Formula 81 was labeled in part: "Each tablet contains 2.6 mg. of the sodium copper soluble salt of chlorophyll." It was alleged to be misbranded in that the name "DPS Formula 81" was a false and misleading device which represented and suggested that the article was efficacious for the following conditions: Hypertension, cardiovascular conditions, toxic conditions, impaired cellular respiration, anemias, and infections.

The DPS Formula 100 was labeled in part: "Each containing: Iron (Ferrous) Sulphate (Dried), 2½ grs.; Liver (Desiccated 1–5), 2 grs.; Stomach Substance (hog). ½ gr.; Pepsin (1–3000), 0.25 grs.; Spleen Subst., ⅓ gr.; Red Bone Marrow ⅛ gr.; Kelp (Laminaria Bulbosa), ⅓ gr.; Hemoglobin, ¼ gr.; Vitamin C, 1000 gammas; Vitamin B_1, 83 gammas; Vitamin B_2, 24 gammas." It was alleged to be misbranded in that the name "DPS Formula 100" was a false and misleading device which represented and suggested that the article was efficacious for the following conditions; Anemias, toxic changes in blood, fatigue, low blood pressure, underweight, hypo-functions of the adrenals, pregnancy, and preoperative and postoperative conditions.

The DPS Formula 103 was labeled in part: "Three Tablets Provide 4000 I. U. Vitamin A 5 Mg. Vitamin E in a base of the following inert desiccated glandular substances; Anterior Pituitary; whole Ovarian; Ovarian Residue; Adrenal Cortex; * * * The Vitamin A is from fish liver oil concentrate; the Vitamin E is from mixed natural tocopherols." It was alleged to be mis-

branded in that the name "DPS Formula 103" was a false and misleading device which represented and suggested that the article was efficacious for the following conditions: Scanty or difficult menstruation, amenorrhea, dysmenorrhea, delayed puberty, delayed menstruation, painful breasts, hot flushes, menopause, ovariectomy, and sexual asthenia.

The DPS Formula 105 was labeled in part: "Three Tablets Provide I. U. Vitamin A 5 Mg. Vitamin E in a base of the following inert desiccated glandular substances: Orchic, Prostate, Whole Adrenal, Anterior Pituitary, Suprarenal Cortex * * * The vitamin A is from fish liver oil concentrate; the vitamin E is from mixed natural tocopherols." It was alleged to be misbranded in that the name "DPS Formula 105" was a false and misleading device which represented and suggested that the article was efficacious as a treatment of impotence, sterility, lowered sex-tone, apathy, mental lethargy, and as a complete support of the male sex function.

The libel alleged further that the devices had acquired the above-described meanings by reason of the fact that the manufacturer of the articles had supplied and, together with his agents and employees and distributors, had disseminated to prospective purchasers of the articles the booklet entitled "DPS DARTELL FORMULAE," which disclosed that the articles were designed and intended for the conditions mentioned above.

The articles known as DPS Formulae 52, 57, 58, 61, and 100 were also misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

On October 16, 1943, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

1125. Misbranding of DPS Formula 56. U. S. v. 8 Bottles of DPS Formula 56. Default decree of condemnation and destruction. (F. D. C. No. 9890. Sample No. 15356–F.)

On May 24, 1943, the United States attorney for the District of Colorado filed a libel against 8 bottles of DPS Formula 56 at Denver, Colo., alleging that the article, which had been consigned by the Dartell Professional Service, had been shipped on or about March 26, 1943, from Los Angeles, Calif.; and charging that it was misbranded.

The article was alleged to be misbranded in that the name "DPS FORMULA 56," appearing on its label, was false and misleading as applied to the product, each gram of which consisted essentially of (label) "Vitamins A, 80,000 USP XI units; Vitamin D, residual amounts as carried with Vitamin A," since the name was a device which represented and suggested to the purchaser that the article was efficacious for the following conditions: Nephritis, conjunctivitis, otitis media, upper respiratory disorders, kidney stones, eye weakness and inflammations, renal and urinary calculi, infection or high fevers, involvement of the mucosae, pregnancy, and lactation; whereas it was not efficacious for such conditions; and that the device acquired such meaning by reason of the fact that the manufacturer had supplied, and, together with his agents, employees, and distributors, had disseminated to prospective purchasers of the article a certain booklet entitled "DPS Dartell Formulae," which disclosed that the article was designated and intended for the above-named conditions.

On July 7, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1126. Misbranding of Papaya Concentrate. U. S. v. 12 Bottles and 4 Bottles of Papaya Concentrate. Default decree of destruction. (F. D. C. No. 10142. Sample No. 43991–F.)

On or about June 28, 1943, the United States attorney for the Western District of Missouri filed a libel against 12 1-quart bottles and 4 1-gallon bottles of Papaya Concentrate at Kansas City, Mo., alleging that the article, which had been consigned on or about April 19, 1943, had been shipped from Chicago, Ill., by Macu Fruit Products; and charging that it was misbranded. The article was labeled in part: "Macu Brand Papaya Concentrate."

Examination disclosed that the article contained papaya pulp, seeds, and sugar.

The article was alleged to be misbranded because of false and misleading statements on its label and in the circular entitled "Drink Papaya (Fruta Bomba)," which represented and suggested that the article, when used as directed, was a rich source of vitamins, was a valuable aid to digestion, and would be of value in such conditions as gastritis, diphtheria, ulcers, bowel disorders, dyspepsia, croup, cancer, and gastric fermentation.

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in the notices of judgment on foods.

On July 30, 1943, no claimant having appeared, judgment was entered ordering that the product be destroyed.

1127. Misbranding of Vbev. U. S. v. 16 Cans of Vbev. Decree of condemnation and destruction. (F. D. C. No. 5457. Sample No. 74285–E.)

On September 25, 1941, the United States attorney for the Southern District of New York filed a libel against 16 10-ounce cans of Vbev at New York, N. Y., alleging that the article had been shipped on or about July 8, 1941, from Jersey City, N. Y., by Healthaids, Inc.; and charging that certain statements in its labeling were false and misleading. The article was labeled in part: "Vbev A Food Beverage A Food Supplement Rich in Natural Vitamin B Complex with Vitamins A, D, and Essential Minerals * * * Purity Products Inc., Jersey City New Jersey Ingredients: Diastasic Malt Syrup, Dextrose, Whole Liquid Milk, Tricalcium Phosphate, Ferric Pyrophosphate—Soluble, Molasses, Natural Vitamin B Complex and Vitamin A and D Concentrate."

Examination disclosed that the article's content of calcium was 796 milligrams per ounce.

It was alleged in the libel (1) that the statement on the label, "Not less than the following values for each ounce of Vbev are maintained through periodic laboratory assays * * * Calcium 1000 milligrams," was false and misleading; (2) that the statement in the labeling of the article to the effect that the article was a new discovery and a new food beverage, developed after years of scientific research and investigation, was false and misleading since the article was merely a combination of well-known foods; and (3) that the statements in the labeling were false and misleading since they represented and implied that the article was efficacious in the cure, mitigation, treatment, or prevention of nervousness, tiredness, sleeplessness, underweight, infections, digestive disorders such as diarrhea, lack of appetite and gas pains, stunted growth, loss of hair, and general failure in physical well-being; and that it was efficacious to form and preserve strong bones and teeth, develop proper skin tone, prevent night blindness, overbrittle fingernails, dietary anemia and many skin disorders, protect eyes from degeneration and cataract, promote proper assimilation of calcium and phosphorus, provide quick energy between meals, aid clotting of blood and red pigmentation of blood, and provide a valuable supplementary supply of natural B complex as well as vitamins A and D and the vital minerals, calcium, phosphorus, iron, and copper. The article was not efficacious for such purposes and conditions.

On June 3, 1942, Purity Products, Inc., claimant, filed an answer denying that the product was misbranded. On March 25, 1943, the case having come on for trial before the court, the claimant having failed to appear to defend, and the Government having presented its proof, the court, on April 14, 1943, found that the article was misbranded as alleged in the libel. Judgment of condemnation was entered on April 22, 1943, and the product was ordered destroyed.

1128. Misbranding of Bates vitamin preparations. U. S. v. 320 Bottles of Vitamin Preparations. Decree of condemnation. Products ordered released under bond for relabeling. (F. D. C. No. 9897. Sample Nos. 3056–F to 3063–F, incl.)

On or about May 13, 1943, the United States attorney for the Western District of Missouri filed a libel against 24 bottles of Bates Natural B Complex, each bottle containing 120 tablets, and 16 bottles of Bates Riboflavin Vitamin B_2 (G), 16 bottles of Bates (Thiamine) Vitamin B_1, 16 bottles of Bates (Nicotinic Acid) Niacin, 16 bottles of Bates (Ascorbic Acid) Vitamin C, 24 bottles of Bates Vitamin A & D, and 208 bottles of Bates Calcium Pantothenate, each bottle of which contained 30 tablets, at Kansas City, Mo., alleging that the articles had been shipped from Chicago, Ill., by Bates Laboratories, Inc., and received by the consignee between February 2 and March 20, 1943; and charging that they were misbranded.

Examination disclosed that the natural B complex tablets contained riboflavin, thiamine, and yeast; that the riboflavin tablets and thiamine tablets contained riboflavin and thiamine respectively; that the niacin tablets contained 10.7 milligrams of niacin each; that the vitamin C tablets contained vitamins grams of ascorbic acid each; that the vitamin A & D tablets contained vitamins A and D; and that the calcium pantothenate tablets contained approximately 10 milligrams of calcium pantothenate each.

The articles were alleged to be misbranded because of false and misleading statements which appeared on the display card headed "Vibrant Health and

Beauty," on circulars headed "We Feature the Complete Line of Bates Vitamin Products," on placards headed "Bates Anti-Grey Hair Vitamins," and on leaflets entitled "Bates Line of Vitamins," and which represented and suggested that the articles singly or in combination were effective treatments for loss of weight, loss of appetite, nervous disorders, skin troubles, bleeding gums, nutritional disorders, indigestion, gray hair, anemia, general body weakness, night blindness, impaired reproduction and lactation, atrophy of glands, teeth decay, nail brittleness, constipation, abdominal distress, gas, nausea, headache, asthenia, damage to heart muscles, and retarded growth.

The articles were also alleged to be misbranded under the provisions of the law applicable to foods, as reported in the notices of judgment on foods.

On June 26, 1943, Bates Laboratories, Inc., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the products were ordered released under bond to be labeled in compliance with the law, under the supervision of an employee designated by the Federal Security Administrator.

1129. Misbranding of Hayden's Caramelized Wheat Germ. U. S. v. 14½ Cases of Wheat Germ. Decree ordering destruction of the product. (F. D. C. No. 10394. Sample No. 48103–F.)

On August 13, 1943, the United States attorney for the Southern District of Ohio filed a libel against 14½ cases, each containing 1 dozen 10-ounce packages, of wheat germ at Athens, Ohio, alleging that the article had been shipped in interstate commerce on or about May 11, 1943, by the Hayden Flour Mills, Inc., Tecumseh, Mich.; and charging that it was misbranded. The article was labeled in part: "Hayden's Caramelized Wheat Germ."

The article was alleged to be misbranded because of false and misleading statements appearing in its labeling which represented that it takes about 300 pounds of wheat to produce 1 pound of the article; that the product would be efficacious in the treatment of constipation, arthritis, poor appetite, retarded growth, lowered vitality, nervousness, poor digestion, gray hair, degeneration of the nervous system, enlargement of the heart, atrophy of the muscles, loss of appetite, stomach ulcer, loss of weight, failure to grow, neuritis, eczema, and nervousness; that it would build resistance; that it contained blood-building minerals; that it would help restore the normal peristaltic action of the intestines and would stimulate the appetite, put pep in the step, help convert the food into energy, aid digestion, promote general health, bring about steadier nerves, stimulate normal growth in infants and children, and help children put on weight and grow faster; that it constituted an essential part of the diet of all children; that it would increase resistance to colds and infections; that it was especially beneficial to nursing mothers; and that it would help prevent baldness and gray hair and cause gray hair to grow in its natural color at the roots. Consumption of the product would not effect the results claimed or suggested; and 1 pound of the product did not represent the wheat germ content of 300 pounds of wheat.

The article was also charged to be misbranded under the provisions of the law applicable to food as reported in notices of judgment on food, No. 5785.

On October 1, 1943, no claimant having appeared, judgment was entered ordering that the product be destroyed.

1130. Misbranding of Sul-Ray Effervescent Mineral Baths. U. S. v. 33 Packages of Sul-Ray Effervescent Mineral Baths. Default decree of condemnation and destruction. (F. D. C. No. 10256. Sample No. 48337–E.)

On July 15, 1943, the United States attorney for the Western District of Kentucky filed a libel against 33 packages of the above-named product at Louisville, Ky., alleging that the article had been shipped on or about May 27, 1943, from New York, N. Y., by the Sante Chemical Co.; and charging that it was misbranded.

Examination disclosed that the article consisted essentially of sulfur with sodium phosphate, carbonate, and borate.

The article was alleged to be misbranded in that the statements in the labeling which represented and suggested that the benefits to be obtained from a visit to mineral springs could be enjoyed at home through the use of the article; and that sulfur in the bath water would be effective in the treatment of rheumatism, arthritis, lumbago, gout, sciatica, various skin conditions, muscular aches and pains, and itching were false and misleading since the benefits from a visit to a mineral spring do not come solely from bathing in the spring water but also include rest and other forms of treatment, and sulfur in the bath water would not be effective in the treatment of the conditions and symptoms named.

On October 11, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1131. Misbranding of Helio Minerals. U. S. v. 3 Dozen Bottles and 3 Dozen Bottles of Helio Minerals. Default decree of condemnation and destruction. (F. D. C. No. 10360. Sample No. 33849–F.)

On August 6, 1943, the United States attorney for the Western District of New York filed a libel against 3 dozen 500-tablet bottles and 3 dozen 160-tablet bottles of Helio Minerals at Buffalo, N. Y., alleging that the article had been shipped on or about June 7 and July 30, 1943, from Detroit, Mich., by the Gordon Service, Inc.; and charging that it was misbranded.

Examination disclosed that the article consisted essentially of seaweed, alfalfa, and parsley leaves, and that 6 tablets, the number directed to be taken in 1 day, would provide only about 1/15 of the minimum daily adult requirement for calcium, 1/60 of the minimum daily adult requirement for phosphorus, 1/5 of the minimum daily requirement of iron for adults and children over 6 years of age, and 1/4 of the minimum daily requirement of iron for children under 6 years of age. The amount of copper provided was essentially inconsequential.

The article was alleged to be misbranded (1) in that the designation in its labeling, "Helio Minerals," was false and misleading as applied to a product which consisted essentially of seaweed, alfalfa, and parsley leaves; (2) in that the statements on its label, "(Dietary Supplement) Contain in Organic (natural) form all of the minerals now known to be essential to nutrition, especially rich in iron, copper," were false and misleading since the article, when taken in accordance with the directions on the label, "3 tablets after breakfast and 3 tablets after evening meal * * * Children over three can be given same amount," would provide but a small fraction of the requirement of adults or children for calcium, phosphorus, and iron, minerals which are known to be essential to nutrition; and also since the article supplied but an inconsequential trace of copper; and (3) in that the statements on its label, "Helio Minerals are prepared in the laboratories of an internationally recognized scientist from his own selection of Macrosystis Pyrifera (Giant Kelp) so as to retain their amazing content of minerals," and "Helio Minerals were prepared to supply minerals in large enough amounts to be of real value," were false and misleading since the article was prepared from seaweed (kelp), alfalfa, and parsley leaves, products which do not contain an unusual proportion of mineral constituents; and, when taken as directed, it would supply but a small fraction of the minerals now known to be essential to nutrition. It was alleged to be misbranded further because of false and misleading statements in a circular entitled "Feel Better Look Better Helio Minerals and Helio Natural B-Complex," which accompanied the article, and which represented and suggested that the article would be effective, either alone or in combination with vitamin B-Complex, to fulfill the promises of benefits stated and implied therein, viz., that it would enrich the blood, soothe the nerves, add energy, repair the body, and increase resistance to disease; that it would make the user feel better and look better; that it would protect the bones and teeth, strengthen the nerves, insure good digestion, keep tissues flexible and active, prevent poor muscular control, neutralize excess acids. produce internal cleanliness, aid in the treatment of rheumatism, skin, and other diseases, help one to sleep better, stimulate the appetite, regulate constipation, and strengthen the heart; that it would prevent neuritis, premature aging, cracking of lips, loss of hair, atrophy of oil glands, and loss of weight; and that it would promote growth, strengthen vision, courage, and morale, restore color to graying hair, and reduce dark coloring in birthmarks and freckles.

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

On September 20, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1132. Misbranding of Floritone. U. S. v. 5¾ Dozen Packages of Floritone. Default decree of condemnation and destruction. (F. D. C. No. 10194. Sample No. 19222–F.)

Examination of a sample of this article showed that it consisted essentially of glucose, dextrin, and whey powder.

On July 7, 1943, the United States attorney for the District of Massachusetts filed a libel against 5¾ dozen packages of Floritone at Boston, Mass., alleging that the article had been shipped on or about April 12, 1943, by the Nature Food Centres, Inc., from Providence, R. I.; and charging that it was misbranded. The

article was labeled in part: "Floritone * * * Manufactured by Vitolectic Food Co. 903 Eddy Street Providence, R. I."

The article was alleged to be misbranded in that the statements appearing on the label, "If an increase in weight is desired take Floritone between meals. If a decrease in weight is desired take Floritone with meals. Large quantities of Floritone are desirable in diarrhea and toxemia," were false and misleading since they represented and suggested that the article would increase and decrease weight, and that it would be effective in the treatment of diarrhea and toxemia, whereas it would not be efficacious for such purposes.

On September 20, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed

1133. Misbranding of Miracle Slenderizing Cream. U. S. v. 16 Jars, 44 Jars, and 7¾ Dozen Jars of Miracle Slenderizing Cream, and 92 Circulars. Default decrees of condemnation and destruction. (F. D. C. Nos. 11801, 12875, 12876. Sample Nos. 57237–F, 57238–F, 63480–F, 70029–F.)

On or about February 16 and July 7 and 15, 1944, the United States attorneys for the District of New Jersey, the District of Utah, and the Northern District of Georgia filed libels against 44 jars of Miracle Slenderizing Cream at Newark, N. J., 7¾ dozen jars at Atlanta, Ga., and 16 jars and 92 circulars at Salt Lake City, Utah, alleging that the article had been shipped within the period from on or about November 16, 1943, to May 22, 1944, by Miracle Products from Chicago, Ill.; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of Epsom salt in an ointment base perfumed with methyl salicylate.

The article was alleged to be misbranded in that certain statements on the jar label and in circulars entitled "The Miracle Plan for a Slender Body," and "For the Preservation and Enhancement of Beauty," which accompanied the article when it was introduced into and while it was in interstate commerce, were false and misleading since they represented and suggested that the article would be effective in the reduction of surplus weight, whereas it would not be effective for that purpose.

It was alleged in the libel filed with respect to the lot seized at Newark that the circulars accompanied the article when introduced into and while in interstate commerce in the following manner: The Miracle Products shipped the circulars on or about November 24, 1943, and on November 16 and 26, 1943, shipped the Miracle Slenderizing Cream at Newark, where the drug and the circulars were brought together for distribution to purchasers; and that the joint shipment and receipt of the drug and the circulars relating thereto for joint distribution constituted a transaction in interstate commerce between the shipper and the consignee whereby the circulars accompanied the article when it was introduced and while it was in interstate commerce.

On April 17, August 8, and September 30, 1944, no claimant having appeared, judgments of condemnation were entered and the product, including the circulars in the Salt Lake City lot, was ordered destroyed.

1134. Misbranding of Nulfey Tablets and Genuine O. B. C. Capsules. U. S. v. 54 Packages of Nulfey Tablets and 54 Packages of Genuine O. B. C. Capsules (and 1 other seizure action against Nulfey Tablets). Default decrees of condemnation and destruction. (F. D. C. Nos. 10328, 11446. Sample Nos. 22654–F, 22655–F, 22867–F.)

On July 27 and December 16, 1943, the United States attorneys for the District of New Jersey and the District of Delaware filed libels against 54 packages of Nulfey Tablets and 54 packages of Genuine O. B. C. Capsules at Atlantic City, N. J., and 61 packages of Nulfey Tablets at Wilmington, Del., alleging that the articles, which had been consigned by the William A. Reed Co. on or about April 26, May 20, and June 10, 1943, had been shipped from Philadelphia, Pa.; and charging that they were misbranded.

Examination of the Nulfey Tablets disclosed that the article consisted essentially of sodium salicylate, sodium biphosphate, methenamine, and plant drugs including a laxative drug.

It was alleged to be misbranded because of false and misleading statements in its labeling which represented and suggested that the article would be effective for the relief of rheumatism, arthritis, neuritis, and sciatica; and that an article that was a diuretic and analgesic would be effective for the relief of kidney dysfunction.

Examination of the Genuine O. B. C. Capsules disclosed that the article consisted essentially of phenolphthalein, caffeine, and clay; that the statement of

ingredients appeared in small type on the bottom of the box containing the article; and that the warnings required by law to appear in the labeling did not appear on the box but were inconspicuously placed in the circular entitled "How To Eat and Get Thin the O. B. C. Way."

It was alleged to be misbranded in that certain statements in its labeling were false and misleading since they represented and suggested that the article would be effective in the reduction of weight, whereas it was merely a phenolphthalein laxative and would not be so effective; and in that the statement of active ingredients and warnings against use and unsafe dosage or methods or duration of administration were not prominently placed upon the labeling with such conspicuousness, as compared with other words, statements, designs, or devices in the labeling, as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

On November 27, 1943, and January 26, 1944, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

1135. Misbranding of Medrex Ointment and Medrex Soap. U. S. v. 634 Dozen Packages and 58 Dozen Packages of Medrex Ointment, and 49 Dozen Cartons of Medrex Soap. Consent decree of condemnation. Product ordered released under bond to be brought into compliance with the law. (F. D. C. No. 10399. Sample Nos. 44455–F to 44457–F, incl.)

On August 14, 1943, the United States attorney for the Southern District of New York filed a libel against 634 dozen 1-ounce packages and 58 dozen 2-ounce packages of Medrex Ointment, and 49 dozen cartons containing 3 bars each of Medrex Soap, at New York, N. Y., alleging that the articles had been shipped on or about April 7, May 12, and June 30, 1942, from Philadelphia, Pa., by the William A. Reed Co.; and charging that they were misbranded.

Examination disclosed that the Medrex Ointment consisted essentially of zinc oxide and petrolatum with small amounts of acetanilid, starch, methyl salicylate, benzoic acid, carbolic acid, and salicylic acid; and that the Medrex Soap was a flesh-colored, perfumed soap containing small amounts of a zinc compound, starch, and salicylic acid.

The articles were alleged to be misbranded because of false and misleading statements in their labeling which represented and suggested that, when used as directed, they were effective for the relief of itching and irritation accompanying eczema, and for the treatment of pimples, scalp eruptions, blotches, and other skin conditions of an external origin.

On December 9, 1943, Martin A. Levitt, trading as the William A. Reed Co., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the products were ordered released under bond to be brought into compliance with the law under the supervision of the Food and Drug Administration.

1136. Misbranding of Ourine. U. S. v. 526 Cartons of Ourine (and 4 other seizure actions against Ourine). Default decree of condemnation and destruction. (F. D. C. Nos. 10178, 11808, 11809, 11859, 11860. Sample Nos. 11250–F, 11254–F, 11259–F, 11590–F, 39537–F, 40312–F, 41433–F, 60709–F.)

Between August 21, 1943, and February 23, 1944, the United States attorneys for the Northern and Southern Districts of California, the Southern District of Texas, and the District of Minnesota filed libels against the following quantities of Ourine: 1,256 bottles at San Francisco, Calif., 37 bottles at Minneapolis, Minn., and 526 cartons and 128 cartons, each containing 1 bottle, at Los Angeles, Calif., and Houston, Tex., respectively; alleging that the article, which had been consigned by the Aurine Co., Inc., had been shipped from Chicago, Ill., within the period from on or about April 6, 1943, to on or about January 26, 1944; and charging that it was misbranded.

Examination disclosed that the article consisted essentially of water, glycerin, boric acid (1.1 percent), carbolic acid (0.18 percent), and traces of alcohol, camphor, clove oil, and extracts of plant drugs.

The article was alleged to be misbranded because of false and misleading statements which appeared in the booklet entitled "The Care of the Ears," and which represented and suggested that the article, when used as directed, would prevent or remedy deafness; that it would effect good hearing by reason of the alleged antiseptic, analgesic, astringent, or anesthetic properties of its ingredients; that it was a safe and appropriate treatment for earaches resulting from bulging or congestion of the tympanic drum; that it would act as a tonic and relieve local catarrhal conditions, pain, soreness, or inflammatory conditions; that it would serve as a protective of the skin and mucous membranes and act as a healing agent; that it would overcome ineffective hearing; that it would give better

hearing; and that it had been successfully used by thousands for the relief of temporary or partial deafness, and constituted an effective means of caring for the ears.

Between September 15, 1943, and June 7, 1944, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

1137. Misbranding of drug products. U. S. v. 7 Cartons of No. 37 Formula GH–5, 4 Cartons of No. 24 Formula GH–1, 15 Cartons of No. 15 Formula GM–15, 9 Cartons of No. 3 Formula GM–4, and 6 Cartons of No. 20 Formula GH–4. Consent decree of condemnation and destruction. (F. D. C. No. 9076. Sample Nos. 13830–F to 13834–F, incl.)

On January 5, 1943, the United States attorney for the Southern District of California filed a libel against 7 large cartons of No. 37 Formula GH–5, 4 large cartons of No. 24 Formula GH–1, 15 large cartons of No. 15 Formula GM–15, 9 large cartons of No. 3 Formula GM–4, and 6 large cartons of No. 20 Formula GH–4, each carton of which contained 3 smaller cartons, at Los Angeles, Calif., alleging that the articles had been shipped on or about December 6, 15, 21, and 29, 1942, from Salt Lake City, Utah, by the Basic Endocrines Sales Co., Inc. (invoiced by Basic Endocrines Sales Co., Inc., Seattle, Wash.); and charging that they were misbranded. There were also at Los Angeles, in the possession of the consignee, a number of books entitled "Theory and Use of Basic Endocrines," booklets entitled "Reference Guide," and leaflets entitled "Basic Endocrines Vol. 1, No. 1," "Basic Endocrines Vol. 1, No. 4," and "Basic Endocrines Vol. 1, No. 6." This printed matter had been received in interstate commerce by the consignee from Seattle, Wash.

Analysis of the No. 37 Formula GH–5 showed that it consisted essentially of capsules containing proteinacious matter, such as dried glandular materials, plant materials, and 0.88 grain per capsule of dicalcium phosphate. It was alleged to be misbranded because of false and misleading statements which appeared in the aforesaid book and booklet, and which represented and suggested that the article would be efficacious in the cure, mitigation, or treatment of functional glycosuria, ketosis, carbohydrate intolerance, pancreatic and duodenal insufficiency, gastro-duodenal ulceration and inflammations, and physiological hyperglycemia; that it was supportive in diabetes mellitus; and that it would assist in alkalinization, increase the blood and tissue calcium, promote healing, and aid in the relief of pain and nervousness. It was alleged to be misbranded further in that the statement on its containers, "No. 37 Formula GH–5," was a false and misleading device, meaning to the purchaser that the article was efficacious for the foregoing conditions referred to in the portions of the book and booklet relating to the article when, in fact, it was not so efficacious. It was alleged to be misbranded further in that the statement on the label, "Each Capsule Contains Pancreas 3 gr., Duodenum 2 gr., Parathyroid 1/10 gr.," was misleading in the absence of a revelation of the material fact that pancreas, duodenum, and parathyroid in the amounts supplied when the article was taken in accordance with the directions on the label, 3 to 6 daily, would not produce any significant therapeutic or physiologic effect.

Analysis of the No. 24 Formula GH–1 showed that it consisted essentially of capsules containing proteinacious matter, such as dried glandular materials, plant materials, and material derived from bile. It was alleged to be misbranded because of false and misleading statements which appeared in the book and booklet and in the leaflet, "Basic Endocrines Vol. 1, No. 6," and which represented and suggested that the article would be efficacious in the cure, mitigation, or treatment of such conditions as hypofunction of the liver, cirrhosis, lack of liver detoxication, duodenitis, constant gas, pseudo-angina, intestinal putrefaction, liver spots, liver and spleen deficiencies, and cardiac irregularities. It was alleged to be misbranded further in that the statement on its containers, "No. 24 Formula GH–1," was a false and misleading device, meaning to the purchaser that the article was efficacious for the foregoing conditions referred to in the portions of the book, booklet, and leaflet relating to the article when, in fact, it was not so efficacious. It was alleged to be misbranded further in that the statement, "Each Capsule Contains: * * * Liver 3½ gr., Spleen 1 gr.," was misleading in the absence of a revelation of the material fact that liver and spleen in the amounts supplied when the article was taken in accordance with the directions on the label, 3 to 6 daily, would not produce any significant therapeutic or physiologic effect.

Analysis of the No. 15 Formula GM–15 showed that it consisted essentially of capsules containing proteinacious matter, such as dried glandular material,

including 0.1 grain per capsule of thyroid, and plant material. It was alleged to be misbranded because of false and misleading statements which appeared in the book and booklet, and which represented and suggested that the article would be efficacious in the cure, mitigation, or treatment of such conditions as general debility, difficult concentration, failing memory, undue worry, sexual neurasthenia, premature senility, advancing years, endocrine deterioration and functional insufficiency, nervous aggravations bringing mental depression, thyroid classified anemias, and those conditions wherein major and glandular support was indicated; and that it would prolong the useful and active period of life. It was alleged to be misbranded further in that the statement on its containers, "No. 15 Formula GM–15," was a false and misleading device, meaning to the purchaser that the article was efficacious for the foregoing conditions referred to in the portions of the book and booklet relating to the article, when, in fact, it was not so efficacious. It was alleged to be misbranded further in that the statement on its label, "Each Capsule Contains: * * * Pituitary (Whole) ¼ gr., Suprarenal ½ gr., Orchic 1½ gr., Prostate ½ gr., Parathyroid 1/40 gr., Pineal 1/60 gr., Ovary ¼ gr., Duodenum 1 gr., Pancreas ½ gr., Heart ½ gr.," was misleading in the absence of a revelation of the material fact that pituitary, suprarenal, orchic, prostate, parathyroid, pineal, ovary, duodenum, pancreas, and heart in the amount supplied when the article was taken in accordance with the directions on the label, 1 to 3 daily, would not produce any significant therapeutic or physiologic effect.

Analysis of the No. 3 Formula GM–4 showed that it consisted essentially of capsules containing proteinacious matter, such as dried glandular material, including 0.1 grain per capsule of thyroid, and plant material. It was alleged to be misbranded because of false and misleading statements which appeared in the book and booklet and in the leaflet, "Basic Endocrines Vol. 1 No. 4," and which represented and suggested that the article would be efficacious in the cure, mitigation, or treatment of chronic hypo-ovarism, sexual apathy, lack of orgasm, sexual maldevelopment, sexual asthenia, irregular menses, cramps during menses, and chronic frigidity; that it was supportive in sterility and following ovarectomy; that it would give necessary metabolic and nerve support; and that it offered complete sex syndrome support. It was alleged to be misbranded further in that the statement on its containers, "No. 3 formula GM–4," was a false and misleading device, meaning to the purchaser that the article was efficacious for the foregoing conditions referred to in the portions of the book, booklet, and leaflet relating to the article when, in fact, it was not so efficacious. It was alleged to be misbranded further in that the statement on its label, "Each Capsule Contains: * * * Anterior Pituitary ⅔ gr., Suprarenal ⅙ gr., Adrenal Cortex ½ gr., Ovary 2½ gr., Mammary ⅓ gr.," was misleading in the absence of a revelation of the material fact that anterior pituitary, suprarenal, adrenal cortex, ovary, and mammary supplied when the article was taken in accordance with the directions on the label, 3 to 6 daily, would not produce any significant therapeutic or physiologic effect.

Analysis of the No. 20 Formula GH–4 showed that it consisted essentially of animal tissues. It was alleged to be misbranded because of false and misleading statements which appeared in the book and booklet and in the leaflet, "Basic Endocrines Vol. 1, No. 1," and which represented and suggested that the article would be efficacious in the cure, mitigation, or treatment of acute toxemia and decreased immunity, toxic migraine, waxy stool, food allergy, renal and hepatic colic, angina, tubular constriction, hives, digestive enzymic deficiency, coronary disease, acute colds, bronchitis, and colic due to the passing of calculi; that it was supportive of psoriasis; that it was efficacious in the final digestion of fats and carbohydrates and in the complete digestion of protein and other food factors; that it was of value in types of food allergy, such as certain migraines, some forms of asthma, hay fever, and eczema; that it would have a relaxing effect upon the urinary apparatus, and would be valuable in spasm or contraction of these parts, and increase the frequency and quantity of urination; and that it would increase weight. It was alleged to be misbranded further in that the statement on its containers, "No. 20 Formula GH–4," was a false and misleading device, meaning to the purchaser that the article was efficacious for the foregoing conditions referred to in the portions of the book, booklet, and leaflet relating to the article when, in fact, it was not so efficacious. It was alleged to be misbranded further in that the statement on its label, "Each Capsule Contains: Adrenal Cortex ¼ gr., and Insulin Free Pancreas 5 gr.," was misleading in the absence of a revelation of the material fact that adrenal cortex and insulin-free pancreas in the amounts supplied when the article was

taken in accordance with the directions on the label, 3 to 12 daily, would not produce any significant therapeutic or physiologic effect.

On July 9, 1943, the Basic Endocrines Sales Co., Inc., claimant, having filed an answer denying that the products were misbranded, and later having consented to the entry of a decree, judgment of condemnation was entered and the products were ordered destroyed.

1138. Misbranding of Anti-Uric. U. S. v. 19 Bottles of Anti-Uric. Default decree of condemnaiton and destruction. (F. D. C. No. 10113. Sample No. 37984–F.)

On June 29, 1943, the United States attorney for the Northern District of Indiana filed a libel against 19 bottles of Anti-Uric at South Bend, Ind., alleging that the article, which had been consigned by the Anti-Uric Company, had been shipped from San Francisco, Calif., on or about April 1, 1943; and charging that it was misbranded.

Examination disclosed that the article consisted essentially of water, alcohol, sugar, and small amounts of extracts of plant drugs.

The article was alleged to be misbranded in that the statements on the bottle labels and in the circular entitled "What About Anti-Uric?" were misleading since such statements represented and suggested that the article was an effective eliminant and stimulant diuretic to the kidneys, and was effective in relieving rheumatic, neuralgic, sciatic, neuritic, and muscular pains, stiff and aching joints, back aches, upset stomach, extreme nervousness, and lumbago, whereas the article was not an effective eliminant and stimulant diuretic to the kidneys and was not effective in relieving the conditions mentioned.

On August 6, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1139. Misbranding of UtraJel. U. S. v. 34 Cartons of UtraJel (and 3 other seizure actions against UtraJel). Decrees of condemnation and destruction. (F. D. C. Nos. 10003, 10019, 10270, 10684. Sample Nos. 14847–F, 23363–F, 36208–F, 48204–F.)

Between May 24 and September 7, 1943, the United States attorneys for the District of Colorado, the Eastern District of Pennsylvania, the Southern District of California, and the Northern District of Ohio filed libels against the following quantities of UtraJel: 34 cartons at Denver, Colo.; 10 packages at Philadelphia, Pa.; and 11 cartons at Los Angeles, Calif., each carton containing 4 tubes; and 8 boxes and 12 boxes at Cleveland and Lorain, Ohio, respectively; alleging that the article, which had been consigned by the Pynosol Laboratories, Inc., had been shipped from on or about April 19 to June 10, 1943, from Chicago, Ill.; and charging that it was misbranded.

Analysis disclosed that the article consisted essentially of pine oil, soap, iodine, and water.

The article was alleged to be misbranded in that the name "UtraJel" was false and misleading since it represented and suggested that the article was safe and appropriate for introduction into the uterus, whereas it was not safe or appropriate for introduction into the uterus, but was unsafe and dangerous, and capable of producing serious or even fatal consequences.

Between July 15 and October 13, 1943, Pynosol Laboratories, Inc., claimant, having filed answers in each of the libel proceedings, orders were entered directing that the Colorado, California, and Ohio cases be removed to the Eastern District of Pennsylvania and consolidated for trial with the case originating in that district. On January 11 and 19, 1944, the claimant having withdrawn its claims and answers, judgments were entered in the Eastern District of Pennsylvania, condemning the product and ordering it destroyed.

1140. Misbranding of Dextro Quinine. U. S. v. 40 Bottles of Quinine. Default decree of condemnation and destruction. (F. D. C. No. 9921. Sample No. 9600–F.)

On May 13, 1943, the United States attorney for the Western District of Louisiana filed a libel against 40 bottles, each containing 1 ounce, of Dextro Quinine at Monroe, La., alleging that the article had been shipped on or about August 27, 1942, from Philadelphia, Pa., via the Railway Express Agency; and charging that it was misbranded.

Examination showed that the article consisted of plant extractive material, about half of which had alkaloidal characteristics; and that the article was not quinine or a dextrorotatory isomer of quinine.

The article was alleged to be misbranded in that the designation "Dextro Quinine," appearing upon its label, was false and misleading since the article was not quinine and was not a dextrorotatory isomer of quinine.

On August 17, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed or otherwise disposed of by the marshal, as provided by law.

1141. Misbranding of Hydraphorus with Cinchona. U. S. v. 33 Bottles of Hydraphorus with Cinchona. Decree of condemnation and destruction. (F. D. C. No. 10082. Sample No. 3286–F.)

On June 17, 1943, the United States Attorney for the District of Kansas filed a libel against 33 bottles of Hydraphorus with Cinchona at Atchison, Kans., alleging that the article had been shipped in interstate commerce on or about October 13, 1942, by the Leon Chemical Co., Springfield, Mo.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of water, a small proportion of phosphoric acid, and only traces of hydrastis and cinchona.

The article was alleged to be misbranded in that the name "Hydraphorus with Cinchona," and the statement in its labeling, "This preparation contains Cinchona, Hydrastis, * * * and glycerine" were false and misleading since the article contained only traces of hydrastis and cinchona, and no glycerine.

On June 21, 1943, the owner-consignee of the product having admitted the allegations in the libel as to misbranding, judgment of condemnation was entered and the product was ordered destroyed.

1142. Misbranding of cream of tartar, powdered alum, aromatic spirit of ammonia, spirit of camphor, and sweet spirit of nitre. U. S. v. 9 Dozen Packages of Cream of Tartar, 8 Dozen Packages of Powdered Alum, 23 Dozen Bottles of Aromatic Spirit of Ammonia, 11 Dozen Bottles of Spirit of Camphor, 23 Dozen Bottles of Sweet Spirits Nitre, and 21 Dozen Packages of Cream of Tartar. Default decrees of condemnation. Products ordered destroyed with the exception of 1 lot of cream of tartar which was ordered delivered to a charitable institution. (F. D. C. Nos. 10781, 11072. Sample Nos. 35613–F, 35631–F to 35635–F, incl.)

On September 16 and November 11, 1943, the United States attorneys for the Southern District of Georgia and the Eastern District of South Carolina filed libels against the above-mentioned products, all of which were at Charleston, S. C., with the exception of 21 dozen packages of cream of tartar at Savannah, Ga., alleging that the articles had been shipped from Jacksonville, Fla., by the Crescent Sales Co., from on or about April 13, 1943, to October 8, 1943; and charging that they were misbranded.

The articles were alleged to be misbranded in that the statements appearing on the labels: (Cream of tartar) "Net Weight 1 Ounce," (powdered alum) "Net Weight 2 Ounces," and (aromatic spirit of ammonia, spirit of camphor, sweet spirit of nitre "½ Fluid Oz.," were false and misleading as applied to the articles, which were short-weight; and in that the labels failed to bear accurate statements of the quantity of contents.

The powdered alum was alleged to be misbranded further in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and it was not labeled as prescribed therein, since it was not labeled to indicate whether the salt was ammonium alum or potassium alum.

A portion of the cream of tartar was alleged to be misbranded further in that its container was so filled as to be misleading since the article occupied only approximately 35 percent of the total capacity of the container. The cream of tartar was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

On October 28, 1943, and January 8, 1944, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed with the exception of one portion of the cream of tartar, which was ordered delivered to a charitable institution.

1143. Misbranding of chemical prophylactics. U. S. v. 955 Packages of Sentry-2-Tube (and 7 other seizure actions against similar products.) Decrees of condemnation and destruction. (F. D. C. Nos. 7809, 7811, 7952, 8035, 8039, 8073, 8074, 8085. Samples Nos. 98340–E, 98702–E, 98704–E, 16838–F, 16839–F, 16902–F, 19682–F, 19688–F, 22710–F, 22711–F.)

Between June 24 and August 17, 1942, the United States attorneys for the District of Vermont, the District of Massachusetts, the Eastern District of Pennsylvania, the District of New Jersey, and the Southern District of New

York filed libels against 955 packages of Sentry-2-Tube at Essex, Vt., 105 tubes of Sentry at Boston, Mass., 285 tubes of Sentry at Philadelphia, Pa., and against the following quantities of Sanitube: 180⅓ dozen tubes at Boston, Mass., 854 tubes at Philadelphia, Pa., 238 packages and 210 tubes at Newark, N. J., and 4,930 tubes at New York, N. Y., alleging that the articles had been shipped within the period from on or about March 24, 1941, to June 30, 1942, from Newport, R. I., by the Sanitube Company, Inc.

Examination of the Vermont lot showed that the article consisted of a white tube labeled "Syphilis," and a blue tube labeled "Gonorrhea." The white tube contained about 1¼ grams of an ointment containing approximately 1 percent of calomel, together with soap; and the blue tube contained approximately 1¼ grams of an ointment containing about 2⅓ percent of calomel together with boric acid and a soap. Examination of the other lots showed that they contained between 0.89 percent and 1.25 percent of calomel, and that they were short weight.

The article in the Vermont lot was alleged to be misbranded (1) in that the statements in its labeling which represented and suggested that it was effective for gonorrhea and syphilis were false and misleading since it was not effective for such purposes; (2) in that it was in package form and its label failed to bear an accurate statement of the quantity of contents; and (3) in that the label for the blue tube failed to state the quantity or proportion of calomel, a mercury derivative, which was present.

The articles in the other lots were alleged to be misbranded (1) in that the statements in their labelings which represented and suggested that they were venereal disease phophylactics were false and misleading since they were not venereal disease prophylactics; (2) in that statements as to the quantity of contents borne on the labels of the tubes were false and misleading since the tubes were short of the declared weight; and (3) in that their labels failed to bear a statement of the quantity or proportion of calomel, a mercury derivative, which was present.

On November 2, 1942, the Sanitube Company, Inc., claimant, having filed with the United States District Court for the Southern District of New York a motion for the consolidation of the various libel proceedings for trial before that court, an order was entered with the consent of the Government for the consolidation of all the proceedings with the exception of the action in the District of Vermont. On November 12, 1943, the claimant having withdrawn its claims and answers, judgment of condemnation and destruction was entered in the consolidated case. On March 9, 1943, the claim and answer having also been withdrawn in the Vermont case, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS FOR VETERINARY USE

1144. Misbranding of calf meal. U. S. v. Frank E. Moore and L. Virginia Moore (Hilltop Farm Feed Co.). Pleas of guilty. Fine of $20, which included both defendants. (F. D. C. No. 10588. Sample No. 8741–F.)

On December 13, 1943, the United States attorney for the District of Minnesota filed an information against Frank E. Moore and L. Virginia Moore, individuals trading as copartners under the firm name Hilltop Farm Feed Co., at Minneapolis, Minn., alleging shipment on or about March 9, 1943, from the State of Minnesota into the State of Wisconsin of a quantity of calf meal that was misbranded. The article was labeled in part: "Hilltop Calf Meal For raising calves economically without milk. Prevents scours and keeps them growing rapidly * * * Guaranteed analysis Protein not less than 24%. Fat—not less than 4.5% Fiber not over 5%." Analysis of the article showed that it was a feed composed of wheat, corn, oats, soy bean products and other vegetable matter, dry milk, bone meal, salt, limestone, anise, iron oxide, and oils, containing not more than 20.94 percent of protein and not more than 3.64 percent fat.

The article was alleged to be misbranded in that the statements "For raising calves, prevents scours and keeps them growing rapidly," were false and misleading since they represented and suggested that the article would be efficacious in the cure, mitigation, treatment, or prevention of scours in calves and would keep calves growing rapidly, whereas it would not be efficacious for such purposes.

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 5687.

On December 13, 1943, the defendants having entered pleas of guilty, the court imposed a fine of $20, which included both defendants.

1145. Misbranding of Gold Bond Chexit and Gold Bond Wurmo. U. S. v. 1,986 Cartons, 1,293 Cartons, and 31 Cans of Gold Bond Chexit, and 498 Cartons and 395 Cartons of Gold Bond Wurmo. Decree of condemnation. Products ordered released under bond. (F. D. C. No. 10316. Sample Nos. 8521–F to 8523–F, incl.)

On July 2, 1943, the United States attorney for the District of Minnesota filed a libel against 1,986 8-ounce cartons, 1,293 1-pound cartons, and 31 3-pound cans of Gold Bond Chexit, and 498 7-ounce cartons and 395 15-ounce cartons of Gold Bond Wurmo at South St. Paul, Minn., alleging that the articles had been shipped from on or about August 12, 1942, to May 24, 1943, by the United Farmers Exchange, from Chicago, Ill.; and charging that they were misbranded.

Analysis disclosed that the Gold Bond Chexit was a pink powder consisting essentially of compounds of calcium and iron, potassium iodide, and plant material including strychnine and fenugreek; and that the Gold Bond Wurmo was a tan powder consisting essentially of sulfur, nicotine, strychnine, ground American wormseed, copper sulfate, and iron sulfate.

The Chexit was alleged to be misbranded because of false and misleading statements in its labeling which represented and suggested that the article was effective in checking any disease condition of livestock, as the name "Chexit" implied; that it would be effective to stop or combat scours in calves, pigs, lambs, colts, and kids, and to prevent shrinkage in livestock during shipping; and that it was a regulator, conditioner, and general tonic.

The Wurmo was alleged to be misbranded because of false and misleading statements in its labeling which represented and suggested that the article would be an effective wormer for any species of worms which infest swine.

On September 9, 1943, the United Farmers Exchange, claimant, having admitted the allegations of the libel, judgment of condemnation was entered and it was ordered that the products might be released under bond, conditioned that they be relabeled or that they be destroyed. The products were destroyed.

1146. Misbranding of Hawk's Fen-R-Tabs, Mul-Ene, and Inhalant Spray. U. S. v. 1,494 Cans of Hawk's Fen-R-Tabs, 150 Bottles of Hawk's Mul-Ene, and 65 Bottles of Hawk's Inhalant Spray. Decree of condemnation. Products ordered released under bond. (F. D. C. No. 10118. Sample Nos. 3586–F to 3588–F, incl.)

On August 23, 1943, the United States attorney for the District of Kansas filed a libel against 964 cans containing 125 tablets each, 497 cans containing 300 tablets each, and 33 cans containing 500 tablets each of Hawk's Fen-R-Tabs, 67 1-quart bottles and 83 1-pint bottles of Hawk's Mul-Ene, and 17 1-pint bottles and 48 ½-pint bottles of Hawk's Inhalant Spray at Atchison, Kans., alleging that the articles had been shipped within the period from May 23 through October 22, 1942, from Cedar Rapids, Iowa, by the Shores Co.; and charging that they were misbranded. It was also alleged in the libel that booklets entitled "Poultry Profits" were shipped on August 31, 1942, by the Shores Co. from Cedar Rapids, Iowa; and that the booklets accompanied the articles when the articles were introduced into and while they were in interstate commerce.

Analysis disclosed that the Hawk's Fen-R-Tabs consisted essentially of phenolsulfonates of sodium, calcium, and zinc and copper arsenite; that Hawk's Mul-Ene consisted essentially of oil of pine, eucalyptus, thymol, acetic acid, hydrochloric acid, emulsifying material, mineral oil, and a saponifiable oil such as castor oil; and that the Hawk's Inhalant Spray consisted essentially of pine oil, camphor, eucalyptol, phenolic compounds (including creosote), and coloring material.

The articles were alleged to be misbranded in that certain statements in the booklet entitled "Poultry Profits" were false and misleading since such statements, as they related to each article, represented and suggested that the articles constituted appropriate and adequate treatments for the conditions and diseases of poultry enumerated therein, namely, in the case of the Fen-R-Tabs, pasting of the vent, worms, roup, colds, respiratory conditions, cholera, pox, typhoid, and bowel troubles; in the case of the Mul-Ene, coccidiosis, worms, mycosis, trichomoniasis, and blackhead; and in the case of the Inhalant Spray, pasting of the vent, roup, colds, respiratory conditions, and pox, whereas the articles, when used as directed, did not constitute appropriate or adequate treatments for such diseases or conditions of poultry.

On September 3, 1943, the Shores Co., claimant, having admitted that the products were misbranded as alleged in the libel, judgment of condemnation was entered and the products were ordered released under bond, conditioned that they be brought into compliance with the law under the supervision of the Food and Drug Administration. The booklets were destroyed.

1147. Misbranding of Kon-Trold Nicotine. U. S. v. 25 Cartons and 17 Cartons of Kon-Trold Nicotine. Default decree of condemnation and destruction. (F. D. C. No. 10521. Sample Nos. 12294–F, 12295–F.)

On September 2, 1943, the United States attorney for the District of Oregon filed a libel against 25 20-ounce cartons and 17 8-ounce cartons of Kon-Trold Nicotine at Portland, Oreg., alleging that the article had been shipped on or about October 19, 1942, and July 2, 1943, from Burbank, Calif., by the Kon-Trold Products Co.; and charging that it was misbranded.

Analysis disclosed that the article was a gray, largely insoluble powder containing nicotine.

The article was alleged to be misbranded in that the statements appearing on its label, "For the control of poultry Round Worms * * * For Round Worm elimination," were false and misleading in that, while a product of this character may have value when used as directed on the label for expelling large roundworms, it would not be effective against all species of roundworms which infest poultry.

On November 1, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1148. Misbranding of McClellan's Nicotine Krumbles. U. S. v. 22 Cartons, 118 Cartons, and 34 Cartons of McClellan's Nicotine Krumbles. Default decree of condemnation and destruction. (F. D. C. No. 10520. Sample No. 12297–F.)

On September 3, 1943, the United States attorney for the District of Oregon filed a libel against 22 2½-ounce cartons, 118 7-ounce cartons, and 34 15-ounce cartons of McClellan's Nicotine Krumbles at Portland, Oreg., alleging that the article had been shipped on or about August 12, 1942, and March 3 and April 28, 1943, from Los Angeles, Calif., by the C. U. McClellan Laboratories Corporation; and charging that it was misbranded.

Examination disclosed that the article was a reddish-brown, largely insoluble powder containing 4.35 percent of nicotine. The label bore the declaration, "Nicotine Sulphate, Rosin, Iron Sulphate, Red Oxide of Iron."

The article was alleged to be misbranded in that the statements appearing upon its label, "Herd Treatment for Hogs for Large Round Worms * * * McClellan's Nicotine Krumbles for hogs is effective," were false and misleading since the article would not be of value as a treatment for large roundworms in hogs; and in that the containers of the 15-ounce size were so filled as to be misleading since they were less than half filled.

On November 1, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1149. Misbranding of Neol and Coridene. U. S. v. 29 Bottles of Neol and 25 Bottles of Coridene. Default decree of condemnation and destruction. (F. D. C. No. 10120. Sample Nos. 5667–F, 5668–F.)

On June 23, 1943, the United States attorney for the Southern District of Iowa filed a libel against 9 16-ounce bottles and 20 6-ounce bottles of Neol, and 6 32-ounce bottles and 19 16-ounce bottles of Coridene at Shenandoah, Iowa, alleging that the articles had been shipped on or about December 12, 1942, from Omaha, Nebr., by the Gland-O-Lac Company; and charging that they were misbranded.

Analysis disclosed that the Neol consisted essentially of thyme oil, eucalyptus oil, creosote, menthol, and a chlorinated phenol dissolved in mineral oil, colored green with chlorophyll; and that the Coridene consisted essentially of an emulsion of cod liver oil and water flavored with thymol and cineol, containing glutamic acid hydrochloride (4.6 percent), total hydrochloric acid (7.5 percent), acetic acid (1.5 percent), copper sulfate (2.4 percent), and arsenic trioxide (0.007 percent—0.03 grain per fluid ounce).

The articles were alleged to be misbranded in that certain statements appearing in the booklet entitled "Gland-O-Lac Manual of Chicken Diseases," and in a circular entitled "This Year . . . try Gland-O-Lac's Formula for Better Chicks," were false and misleading since such statements, as they related to each article, represented and suggested that the articles constituted appropriate and adequate treatment for the conditions and diseases of poultry enumerated therein, namely, in the case of the Neol, white diarrhea (pullorum disease), respiratory diseases, common colds, contagious coryza, bronchitis, brooder pneumonia, nutritional roup, laryngotracheitis, coryza, simple bronchitis, bacterial bronchitis, colds, and roup; and in the case of the Coridene, white diarrhea, mycosis, erosions of gizzard lining, non-specific infections, coccidiosis, and fowl typhoid, in addition to aiding digestion, stimulating the liver, aiding in the production of red blood coloring matter in certain conditions, and helping avoid

constipation, whereas the articles, when used as directed, did not constitute appropriate or adequate treatment for such diseases or conditions of poultry.

On July 28, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1150. Misbranding of Dr. MacDonald's Vitamized Egg Mash Maker and Chick & Growing Mash Maker, and Dr. MacDonald's Vitamized Metabolators for Swine, Calves, Beef Cattle, and Sheep. U. S. v. 9 Bags of the Egg Mash Maker, 8 Bags of the Chick & Growing Mash Maker, and the following quantities of the Vitamized Metabolators: For Swine, 101 Bags; for Calves, 1 Bag; for Beef Cattle, 27 Bags; for Sheep, 10 Bags. Decrees of condemnation. Product ordered released under bond for relabeling. (F. D. C. Nos. 10951, 11085. Sample Nos. 8241–F, 8565–F, 8566–F, 8568–F to 8570–F, incl.)

On October 22 and November 10, 1943, the United States attorney for the District of Minnesota filed libels against a total of 156 100-pound bags of the above-named products at St. Paul, Minn., alleging that they had been shipped in interstate commerce on or about March 20, May 14, and September 22, 1943, by the Vitamized Feed Company, Fort Dodge, Iowa; and charging that they were misbranded.

Examination of the Egg Mash Maker showed that it consisted of ground limestone, salt, charcoal, sulfur, and small amounts of iron sulfate, copper sulfate, sodium bicarbonate, potassium iodide, oil, and plant material including ginger. The iodine content was not more than 0.03 percent. It was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that the article, when fed to poultry, was effective to produce high egg production, increase vitality, insure greater hatchability of eggs, improve utilization of foods, and prevent or correct many nutritional deficiency diseases, were false and misleading since the article was not so effective.

Examination of the Chick & Growing Mash Maker showed that it consisted essentially of ground limestone, salt, charcoal, sulfur, and small proportions of iron sulfate, iron oxide, copper sulfate, sodium thiosulfate, sodium bicarbonate, potassium iodide, oil, yeast, and plant material including a cereal, and ginger. It was alleged to be misbranded because of false and misleading statements in its labeling which suggested and implied that the article was vitamized; that it would stop chick losses; that it would prevent any disease condition of chicks or chickens; that it would help to keep the chicks in good health; that it would help to produce healthy, mature birds in the shortest possible time; that it was a balancer of feeds; that it would reduce mortality due to unbalanced feeds; that it would increase egg production and build greater resistance to disease; that it would help guard against chick mortality; that it would help to grow chicks at a faster rate in a shorter period of time at less cost; that it would increase the flow of digestive juices and body secretions; that it would build strong, vigorous, thrifty chicks; that it would promote strong bone structure, rapid growth, and improve flock health and vigor; that it would ward off nutritional deficiency diseases; and that it would build up resistance against infectious diseases. The use of the article would not effect the results suggested or implied by such statements.

Examination of the Metabolator for Swine showed that it consisted essentially of ground limestone, salt, charcoal, sulfur, and small proportions of iron sulfate, sodium thiosulfate, copper sulfate, sodium bicarbonate, potassium iodide, oil, yeast, and plant material including fenugreek and a cereal. It contained not more than 0.01 percent of iodine. It was alleged to be misbranded because of false and misleading statements appearing in its labeling which suggested or implied that it was vitamized; that it would promote metabolism; that it would prevent death losses; that it would insure against losses due to any cause; that it would prevent pigs from developing white and black scours; that it was effective in the treatment of the disease condition known as necro; that it would increase benefits of home-grown grains; that it would help improve health of stocks through better nutrition; that it would increase the profits from swine; that it would increase reproductive ability; that it would insure large litters of husky pigs; that it would improve the digestive ability of feeds and increase the flow of saliva and digestive juices; that it would produce a better utilization of the feed; that it would prevent the disease conditions known as scours, pneumonia, worms, necro enteritis, or any other contagious diseases; that it would help produce big, strong, healthy litters; that it would increase the milk production of sows; that it would help produce strong and healthy pigs; that it would save pigs; and that it would help to combat scours, necro, worms, or other pig dis-

eases. The use of the article would not effect the results suggested or implied by such statements.

Examination of the Metabolator for Calves showed that it consisted essentially of ground limestone, charcoal, sulfur, salt, and small proportions of iron sulfate, sodium thiosulfate, copper sulfate, sodium bicarbonate, oil, yeast, and plant material, including fenugreek, anise, and a cereal. It contained not more than 3.11 percent of phosphorus and not more than 0.038 percent of iodine. It was alleged to be misbranded in that the statements appearing in its labeling which suggested or implied that it was vitamized; that it would promote metabolism; that it would prevent or cure scours in calves; and that it would prevent scours due to vitamin A and B deficiencies, were false and misleading since the use of the article would not effect the results suggested or implied by such statements.

Examination of the Metabolator for Beef Cattle showed that it contained charcoal, ground limestone, salt, sulfur, and small proportions of iron sulfate, copper sulfate, sodium thiosulfate, sodium bicarbonate, potassium iodide, oil, and plant material, including fenugreek, anise, ginger, and a cereal. It contained 0.040 percent of iodine. It was alleged to be misbranded because of false and misleading statements appearing in its labeling which suggested or implied that it was vitamized; that it would promote metabolism; that it would help promote better digestion and assimilation of feed; that it would help keep the animal on full feed; that it would help stimulate the flow of saliva and other important digestive juices; that it would produce rapid growth, health, and reproduction; that it would promote nutritional balance; and that it would promote smoother or more even flesh and a glossy coat of hair. The use of the article would not effect the results suggested or implied by such statements.

Examination of the Metabolator for Sheep showed that it consisted essentially of ground limestone, salt, charcoal, sulfur, and small proportions of iron sulfate, sodium thiosulfate, copper sulfate, sodium bicarbonate, potassium iodide, oil, yeast, and plant material including anise, fenugreek, ginger, and a cereal. The iodine content was not more than 0.038 percent. It was alleged to be misbranded in that the statements appearing in its labeling which suggested or implied that it was vitamized and would promote metabolism; that it would make sheep, wool, and mutton production profitable; that it would produce husky lambs; that it would increase the milk flow at lambing time; that it would help the reproductive processes; that it would produce better utilization of food; that it would stimulate the appetite; and that it would produce a fine finish and high-quality carcass, were false and misleading since the use of the article would not effect the results suggested or implied by such statements.

The Chick & Growing Mash Maker was also alleged to be misbranded, and the other articles were also alleged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in the notices of judgment on foods, No. 5689.

On December 14 and 22, 1943, the Vitamized Feed Company, claimant, having admitted the material allegations of the libels, judgments of condemnation were entered and the products were ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

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PRODUCTS

SHIPPERS AND MANUFACTURERS

U. S. GOVERNMENT PRINTING OFFICE: 1945

D. D. N. J., F. D. C. 1151-1200 Issued June 1945

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

1151–1200

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

WATSON B. MILLER, *Acting Administrator, Federal Security Agency.*
Washington, D. C., April 5, 1945.

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DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

1151. Adulteration and misbranding of Eli-606 Capsules and misbranding of Stero-Uteroids. U. S. v. Charles A. Ainsworth (Ainsworth Specialty Co.). Plea of guilty. Fine, $350. (F. D. C. No. 10542. Sample Nos. 3311–F, 37824–F.)

On September 17, 1943, the United States attorney for the Western District of Missouri filed an information against Charles A. Ainsworth, trading as the Ainsworth Specialty Co., Kansas City, Mo., alleging shipment from the State of Missouri into the State of Oklahoma, on or about January 21, 1943, of a quantity of Eli-606 Capsules, and into the State of Illinois from on or about July 24, 1941, to October 17, 1942, of quantities of Stero-Uteroids.

Analysis of the Eli-606 Capsules disclosed that the article contained per capsule 0.154 grain of sodium cacodylate, and not more than 0.89 grain of methenamine, 0.386 grain of acetanilid, 0.49 grain of calcium phosphate, and 0.476 grain of sodium phosphate.

The article was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess since it was represented to contain in each capsule ½ grain of sodium cacodylate, 2 grains of methenamine, and 1 grain each of acetanilid, calcium phosphate, and sodium phosphate, whereas it contained smaller amounts of those substances. It was alleged to be misbranded in that the statements on its label, "Formula: Soda Cacodylate ½ Gr. * * *

*For presence of a habit-forming narcotic without warning statement, see Nos. 1152, 1163; deceptive pack; aging, No. 1155; failure to bear accurate statement of quantity of contents, Nos. 1156, 1182, 1190, 1191, 1196; omission of, or unsatisfactory, ingredients statement, Nos. 1157, 1188, 1196; inconspicuousness of, or unsatisfactory, required label information, Nos. 1158, 1160; imitation of another drug, No. 1190; cosmetics, subject to the drug provisions of the Act, Nos. 1193, 1194.

Methenamine 2 Grs. * * * Acetanilide. Calc. Phosphate. Sodium Phosphate aa. 1 Gr. * * *," were false and misleading; and in that the statements "Formula * * * to make one 10 grain capsule," appearing on its label, and "FORMULA * * * for each 10 gr. capsule," appearing in the circular accompanying the article, were false and misleading since they represented and suggested that each of the capsules contained 10 grains of the article, whereas, each capsule contained a smaller amount. It was alleged to be misbranded further because of false and misleading statements in its labeling which represented and suggested that the article would be efficacious as an antiluetic, urinary antiseptic, alterative, blood cleanser, blood tonic, and as a substitute for or supplement to intravenous medication in luetic-syphilitic cases; and that it would be efficacious in the cure, mitigation, treatment, or prevention of gonorrhea, venereal discharges and infections, blood dyscrasias, malarial poisoning, anemias, lowered blood count, hepatic (liver) torpor, gallstones, and urinary infections, generally.

Analysis of the Stero-Uteroids disclosed that they consisted essentially of small proportions of zinc sulfate, plant material including an alkaloid-bearing drug, ichthammol, and a minute amount of iodine incorporated in lanolin.

The Stero-Uteroids were alleged to be misbranded in that the article would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, and suggested in the labeling, since the name of the article, "Stero-Uteroids," the manner of packaging, i.e., collapsible metal tube with key, and the directions of a portion, "Apply with catheter under aseptic conditions," suggested the introduction of the article into the uterus, whereas the article, when introduced into the uterus, would be dangerous. It was alleged to be misbranded further in that the statements (portion), "Stero-Uteroids * * * to be used only by or on the prescription of a physician," and (remainder) "Stero-Uteroids * * * Directions: Apply with catheter under aseptic conditions. For administration by physician only," appearing in the labeling, were false and misleading since they represented and suggested that the article was a safe medicament for introduction into the uterus, whereas it was not a safe medicament for introduction into the uterus.

On October 11, 1943, the defendant entered a plea of guilty and the court imposed a fine of $50 on each of the 7 counts, a total fine of $350.

1152. Adulteration and misbranding of Trems. U. S. v. 19½ Dozen Packages and 130 Packages of Trems. Default decrees of condemnation and destruction. (F. D. C. Nos. 9559, 11654. Sample Nos. 712–F, 59514–F.)

On March 22, 1943, and January 18, 1944, the United States attorneys for the Northern District of Illinois and the Eastern District of Michigan filed libels against 19½ dozen packages and 130 packages of Trems at Detroit, Mich., and Chicago, Ill., respectively, alleging that the article had been shipped on or about February 10 and August 31, 1943, by Trems, Inc., St. Louis, Mo.; and charging that it was misbranded and that a portion was adulterated.

Examination disclosed that the article was in the form of tablets which contained phenobarbital, aspirin, and caffeine. One shipment contained 1 grain and the other contained 0.77 grain of phenobarbital per tablet.

The article was alleged to be misbranded in that it was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, "Dosage: Sleeplessness—For adults, two tablets 20 minutes before retiring. * * * Other Symptoms—One to two tablets as required," since the article contained phenobarbital, a drug which cannot be administered with safety except under competent supervision, and the directions which appeared in the labeling did not provide for any limitation in the dosage, but implied that the article might be taken as frequently as desired with safety. It was alleged to be misbranded further in that it was for use by man and contained a chemical derivative of barbituric acid, phenobarbital, which derivative has been by the Federal Security Administrator, after investigation, found to be, and by regulations designated as, habit-forming, and its labeling failed to bear the statement "Warning—May be habit forming," in juxtaposition with the name and quantity or proportion of the derivative of barbituric acid. In addition, in the case of the Chicago lot, its label failed to bear, as the regulations specify, the name and quantity or proportion of phenobarbital and the statement "Warning—May be habit forming" immediately following, without intervening written, printed, or graphic matter, the name by which the article was titled.

The article in the Detroit lot was alleged to be misbranded further in that the statement, "Each Tablet Contains Phenobarbital 1 Gr.," appearing on its label, was false and misleading as applied to an article which did not contain, in each tablet, 1 grain of phenobarbital. It was alleged to be adulterated in that its strength differed from that which it was represented to possess.

On February 21 and May 19, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

1153. Adulteration and misbranding of Akerite Glycerin Alternate B–100 (glycerin substitute or alternate). U. S. v. Akerite Chemical Works, Inc. Plea of guilty. Fine, $3,004 and costs. (F. D. C. No. 9679. Sample Nos. 6594–F, 2333–F, 23346–F.)

On October 25, 1943, the United States attorney for the Northern District of Illinois filed an information against the Akerite Chemical Works, Inc., Chicago, Ill., alleging shipment of quantities of the above-named product from the State of Illinois into the States of Missouri and Pennsylvania on or about September 9, 1942, and January 20 and February 4, 1943.

It was also alleged in the information that prior to the dates of the 1943 shipment the defendant represented the article as a nontoxic substitute for glycerin by causing to be prepared and distributed a circular entitled "Akerite Glycerin Substitute," which contained the following statements: "Akerite Glycerin Substitute is an aqueous solution derived from dextrin, starch and corn sugar by a special process. It is non-toxic"; and that prior to the date of the 1942 shipment the defendant represented the article as a nontoxic alternate for glycerin by means of a written communication, addressed by the defendant to the consignee, which contained the following statement: "Glycerin Alternate * * * Akerite Glycerin Alternative, an aqueous nontoxic liquid derived mainly from corn."

The article was alleged to be adulterated in that it was represented as a nontoxic substitute or nontoxic alternate for glycerin, which is a nonpoisonous substance, whereas the article consisted in large part of diethylene glycol, a poisonous chemical compound. It was alleged to be further adulterated in that a toxic substance, i. e., a substance containing diethylene glycol, had been substituted in whole or in part for the article.

A portion of the article (two shipments) was alleged to be misbranded because of false and misleading statements on the labels which represented and suggested that it was a substitute for glycerin, a nonpoisonous substance.

It was also alleged in the information with respect to the two shipments that the article was a new drug since it was not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions suggested in its labeling, i. e., "Glycerin Substitute," and application filed pursuant to the law was not effective with respect to the article.

On December 30, 1943, the defendant having entered a plea of guilty, the court imposed a fine of $1,000 on each of the 3 counts charging adulteration, and a fine of $1 on each of the other counts, a total fine of $3,004 plus costs.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

1154. Misbranding of Sano. U. S. v. William J. Nassano (Sano Medicine Co.) Plea of guilty. Fine, $250 and costs. (F. D. C. No. 10619. Sample No. 46330–F.)

On February 3, 1944, the United States attorney for the Northern District of Ohio filed an information against William J. Nassano, trading as the Sano Medicine Co., Cleveland, Ohio, alleging shipment of a quantity of Sano on or about February 7, 1943, from the State of Ohio into the State of Virginia.

Analysis disclosed that the article consisted of a brown liquid with sediment, containing water, alcohol, and plant extractives, including emodin-bearing drugs and a trace of unidentified alkaloids.

The article was alleged to be misbranded because of false and misleading statements appearing in its labeling which represented and suggested that the article was a diuretic and a tonic; that it would be efficacious as an internal medicine and aid in the relief of rheumatism; that it would assist in eliminating uric acids

and toxins from the system; and that it would be efficacious in removing the cause of uric acids and toxins in the system.

It was alleged to be further misbranded in that its labeling did not bear adequate directions for use since the directions provided for taking the article three times each day, whereas the article was a laxative and should be taken only occasionally and as needed; and in that its labeling failed to warn that the article should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present, or that frequent or continued use might lead to a dependence on laxatives to move the bowels.

On March 1, 1944, the defendant entered a plea of guilty and the court imposed a fine of $250 and costs.

1155. Misbranding of Hamby's Dawson Springs Water. U. S. v. Dawson Springs Water Co., Inc., and William R. Whitford. Pleas of guilty. Fines, $125 plus costs against each defendant. (F. D. C. No. 10617. Sample No. 42273–F.)

On February 15, 1944, the United States attorney for the Western District of Kentucky filed an information against the Dawson Springs Water Co., Inc., Dawson Springs, Ky., and William R. Whitford, president, alleging shipment on or about March 25, 1943, from the State of Kentucky into the State of Tennessee of a quantity of the above-named product.

Analysis disclosed that the article consisted essentially of Epsom salt and sodium sulfate, with small proportions of sodium chloride and calcium sulfate, and water. The carton in which the bottle containing the article was packed was materially larger than necessary.

The article was alleged to be misbranded (1) since it was a laxative and its labeling failed to warn that it should not be used when abdominal pains, nausea, vomiting, or other symptoms of appendicitis were present, and that frequent or continued use might result in dependence on laxatives to move the bowels; (2) in that its container was so made, formed, and filled as to be misleading; and (3) in that the statements appearing in its labeling which represented and suggested that the article consisted essentially of natural mineral spring water and derived its physiological activity principally from water obtained from natural mineral springs were false and misleading since the article consisted essentially of magnesium sulfate (Epsom salt) and sodium sulfate dissolved in water, and it derived its physiological activity in greater part if not entirely from its content of added magnesium sulfate and sodium sulfate.

The article was alleged to be misbranded further because of false and misleading statements in its labeling which represented and suggested that it would aid in natural elimination; that it would be effective as an alterative and blood tonic; that it would be healing to the mucous membrane; that it would be valuable in the treatment of all diseases of the teeth, bone, skin, and blood; that it would aid digestion and be of value in the treatment of diabetes; that it would appreciably neutralize acid in the stomach; that it was of value as a liver medicine and would act on the kidneys and aid in the treatment of rheumatism and gout; that it would stop secretion of uric acid, correct phosphate in the urine, and be of value in the treatment of Bright's disease; that it was a diuretic for rheumatism, gout, gravel, dropsy, gall stones, and similar conditions indicated by the abbreviation "etc."; that it was a tonic and nerve sedative, and would promote secretion of urine and be of value in the treatment of gastric disturbances, stomach troubles, indigestion, and the similar conditions indicated by the abbreviation "etc."; and that it was a valuable kidney remedy.

On May 1, 1944, the defendants having entered pleas of guilty, the court imposed a fine of $125 plus costs against the corporate defendant, and a fine of $125 plus costs against the individual defendant.

1156. Misbranding of Balm and Kru-Lax. U. S. v. Carl Fred Krueger (Oriental Laboratory). Plea of guilty. Fine, $200. Sentence of 6 months in jail suspended and defendant placed on probation for 3 years. (F. D. C. No. 10625. Sample Nos. 46414–F, 46415–F.)

On January 29, 1944, the United States attorney for the Eastern District of Missouri filed an information against Carl Fred Krueger, trading as the Oriental Laboratory, St. Louis, Mo., alleging shipment from the State of Missouri into the State of Illinois of a quantity of Balm on or about March 22, 1943, and a quantity of Kru-Lax on or about April 8, 1943.

Analysis of the Balm disclosed that it consisted of small proportions of carbolic acid, creosote, camphor, and pine tar, incorporated in a base of petrolatum.

The article was alleged to be misbranded (1) in that its labeling failed to bear adequate warnings against use and against unsafe methods of application, since the article contained carbolic acid, and its labeling failed to warn that a bandage should not be used when the article was applied to fingers and toes, and that the article should not be applied to large areas of the body; (2) in that its label failed to bear an accurate statement of the quantity of contents since the labels on the bottles containing the article represented that they contained 1 ounce, whereas the bottles contained less than that amount; and (3) in that the statements on its label which represented and suggested that the article was an all-purpose ointment and would be efficacious in the cure, mitigation, or treatment of all burns, cuts, sores, and all other skin disorders, were false and misleading since the article was not an all-purpose ointment and would not be useful in many conditions for which other ointments are used, and would not be an efficacious treatment for the more serious burns or cuts, or for sores or the numerous varieties of skin disorders.

It was alleged to be misbranded further because of false and misleading statements on its labeling in regard to the "Kru-Lax," which represented and suggested that the Kru-Lax contained no drugs and would be efficacious for the purposes described below.

Analysis of the Kru-Lax disclosed that it consisted essentially of plant material including laxative drugs, Epsom salt, and small proportions of buchu, licorice, gentian, anise, and sulfur.

It was alleged to be misbranded because of false and misleading statements appearing in its labeling which represented and suggested that it contained no drugs and would be efficacious in the cure, mitigation, treatment, or prevention of dizziness, indigestion, tired feeling, colic, stomach trouble, foul breath, loss of appetite, coated tongue, rheumatism, and a great majority of human ailments; that it would be efficacious in the treatment of biliousness and of conditions of the system where a gentle stimulus to the action of the bowels was desired; that it would give immediate relief in conditions arising from inactivity of the liver; that it would make the user snap back to the feeling of "rarin to go" fitness; that it would eliminate the left-over wastes that hold one back; and that it would be efficacious to make weak bowels healthy and restore their muscular contraction. The article was alleged to be misbranded further in that its labeling failed to bear adequate directions for use, since the directions on the carton, "Dose: Take regular at bedtime, one-third teaspoonful in one-fourth glass water," and "In taking Kru-Lax start with one-third teaspoonful * * * on the following day, if it causes more than two evacuations, reduce the dose accordingly, or it may be increased if necessary," implied that the article should be taken repeatedly or continuously, whereas the article was a laxative and should not be used repeatedly or continuously since such use might result in dependence upon laxatives to move the bowels.

On March 7, 1944, the defendant having entered a plea of guilty, the court imposed a fine of $100 on each of 2 counts and sentenced the defendant to serve 6 months in jail. The jail sentence was suspended and the defendant was placed on probation for 3 years.

1157. Misbranding of Special Formula Tablets #2. U. S. v. 1 Drum of Special Formula Tablets #2. Tried to the court. Judgment for the Government. Decree of forfeiture and destruction. Judgment affirmed on appeal to the Circuit Court of Appeals. Application for writ of certiorari denied by the Supreme Court. (F. D. C. No. 5800. Sample No. 51270–E.)

On September 22, 1941, the United States attorney for the District of Massachusetts filed a libel against 1 drum containing 99,940 tablets of the above-named product at Boston, Mass., alleging that the article had been shipped on or about July 3 and August 7, 1941, from Buffalo, N. Y., by the Arner Co., Inc.; and charging that it was misbranded.

Analysis disclosed that the article contained an extract of a laxative plant drug such as cascara sagrada, sodium bicarbonate, and sodium citrate.

The article was alleged to be misbranded (1) in that its label failed to bear the common or usual names of the active ingredients in the preparations; (2) in that its labeling bore no directions for use; and (3) in that its labeling failed to bear adequate warnings, since the labeling did not warn the purchaser that the use of the article in case of abdominal pain, nausea, vomiting, or other symptoms of appendicitis might be dangerous and that frequent or continued use of the article might result in dependence upon laxatives to move the bowels.

On March 31, 1943, Paul Case, Brockton, Mass., and the Arner Co., Inc., having appeared as claimants, and the case having been submitted to the court on an agreed statement of facts, the following opinion was handed down by the court:

SWEENEY, *District Judge:* "This is a libel for the condemnation of certain drugs described in the libel as Special Formula Tablets No. 2. Paul Case has filed an answer asserting ownership of the goods seized. The Arner Co., Inc., in its answer, asserts that as agent for Case it shipped the goods in two large drums, and at the time of shipment it had in its possession a duly executed guarantee from Case that the drugs shipped would be packaged and labeled to conform to the law before sale to the consumer. The parties have agreed on the facts, and the real question of law is whether this shipment was exempt under the regulations.

"The tablets were manufactured in Buffalo, New York, by The Arner Co., Inc., for Paul Case of Brockton, Massachusetts, under a special formula owned by Case. They were labeled Special Formula Tablets No. 2 upon shipment, and, at all times thereafter and when seized, were in the container in which they had been shipped, and were not packed for retail sale. They were received by Case, and it was upon his premises that they were seized under 21 U. S. C. A. § 334 by the United States Marshal, who found one drum containing about 40,000 tablets of Special Formula No. 2. The parties agree that a representative sample of the tablets shows them to be 'sugar coated tablets containing sodium citrate, sodium bicarbonate and extract of a plant drug, such as cascara sagrada.' The Arner Co., Inc., is not the operator of the establishment where the tablets were to be labeled or repackaged.

"The case is one of first impression. The claimants contend that they are not required by the law to label the drugs, because they are in bulk. The statute requires all shipments to be properly labeled, and a special exemption for goods in bulk would not have been made in Section 353 (a), (21 U. S. C. A. § 353 (a) if bulk packages were not covered by the Act. *Strong, Cobb & Co.* v. *United States*, 103 F 2d 671, was a prosecution under the old Pure Food and Drug Act for drugs shipped in bulk. The present law is no narrower.

"There are two exemptions in Regulations § 2.107 (a) under Section 353 (a), 21 U. S. C. A. § 353 (a). The first is where the person who introduces the goods into interstate commerce is the operator of the establishment where the goods are to be repackaged. It is to be noted that the Regulation is addressed to the shipper and not the operator of the establishment. The Arner Co., Inc., manufactured and shipped the goods, and admits it is not the operator of the establishment where the drugs were to be repacked. Case claims that he introduced the goods into commerce through his agent, The Arner Co., Inc. There is no exemption in the regulations where the operator of the establishment that repacks introduces the goods into interstate commerce through an agent designated for that purpose. The exemption is to a qualified shipper, and the only shipper who can qualify is one who is the operator of the repacking plant. Further, the commercial agency of The Arner Co., Inc., to ship the goods was not such an agency as a law whose purpose is to guard the public health can notice. It does not avoid the scope of interstate commerce. *Santa Cruz Fruit Packing Company* v. *National Labor Relations Board*, 303 U. S. 453.

"The second exemption requires an agreement between the parties 'containing such specifications for the processing, labeling, or repacking, as the case may be, of such drug or device in such establishment as will insure, if such specifications are followed, that such drug or device will not be adulterated or misbranded within the meaning of the Act upon completion of such processing, labeling or repacking.' The agreement submitted by the claimants contains no specifications as to the label on the retail package, and cannot be said to conform to the Regulation.

"I conclude that the seized shipment was not within the exempted classes, and, accordingly, was liable to seizure and forfeiture.

"A decree in accordance with the above may be submitted."

On April 6, 1943, judgment of forfeiture was entered and the product was ordered destroyed. Notice of appeal was filed by the claimants on April 13, 1943, and on May 4, 1944, the United States Circuit Court of Appeals for the First Circuit handed down the following opinion which affirmed the judgment of the District Court:

MAHONEY, J.: "This is a libel for the condemnation of certain drugs alleged to have been misbranded in violation of the Act of Congress of June, 1938, c.

675, 52 Stat. 1040, 21 U. S. C. §§ 301–392, known as the Federal Food, Drug, and Cosmetic Act. The drugs were manufactured in Buffalo, New York, by The Arner Co., Inc., for Paul Case of Brockton, Massachusetts, under a special formula owned by Case and were shipped f. o. b. from Buffalo by Arner to Case in Brockton where they were seized on the premises of the latter while in the bulk package in which they had been shipped. The package, a drum of about 40,000 tablets, was labeled 'Special Formula Tablets No. 2—The product contained herein must be packaged and labeled at point of destination before sale.' The drugs were to be repackaged by Case for the retail trade. The libel alleged that the drugs were misbranded in that the label did not contain the required names of the active ingredients of the preparation and contained no statement of warning and directions. The appellants denied that the drugs were misbranded and asserted that they were exempt from the labeling requirements of the Act as they were in bulk package, not retail packages and not intended for sale until repackaged and labeled. Paul Case, in his answer, asserts ownership of the goods. The Arner Company asserts that it shipped the goods as agent for Case and that at the time of shipment it had in its possession a duly executed guarantee from Case that the drugs shipped would be packaged and labeled to conform to the law before sale to the consumer. It is agreed that the composition of said Special Formula Tablets No. 2 is as follows: sugar coated tablets containing sodium citrate, sodium bicarbonate and extract of a plant drug, such as cascara sagrada. The Arner Company is not the operator of the establishment where the tablets were to be labeled or repackaged. The Arner Company and Paul Case here appeal from the decree of forfeiture. They contend (1) that 'labeling' as defined in the statute does not apply to containers of bulk shipments; (2) that regulation (a) (2) of § 503 (a) (21 U. S. C. § 353) is invalid because it exceeds the limitations of the statute; (3) that if said regulation is not invalid, it has been sufficiently complied with; (4) that the bulk package herein involved is especially exempted under regulation (a) (1) of § 503 (a).

"Section 301 (a) (21 U. S. C. § 331) prohibits 'the introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded'. By § 502 (21 U. S. C. § 352) it is provided that a drug shall be deemed misbranded: '(e) If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; and (2), in case it is fabricated from two or more ingredients, the common or usual name of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including, whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein. . . .'[1]

"Section 201 (k) (21 U. S. C. § 321) in defining 'label' provides: 'The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.'

"Contrary to appellants' contention, this section does not indicate that the labeling requirement applies only to retail packages and not to bulk shipments. That could not be the proper interpretation in view of § 503 (a) which directs the Administrator to promulgate regulations exempting such shipments on certain conditions: 'The Administrator is hereby directed to promulgate regulations exempting from any labeling or packaging requirement of this chapter drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such

[1] Also pertinent to the libel is: "(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users. . . ."

drugs and devices are not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repacking establishment.'

"The first clause of § 201 (k)—'The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article'—thus must refer to an immediate container of an article shipped in bulk as well as the retail package and the second clause in referring specifically to retail packages must be an extension of labeling requirements and not a limitation. If § 201 (k) were not intended to apply to bulk shipments, § 503 (a) would be purposeless and meaningless. There would be no need to provide for the promulgation of regulations exempting bulk shipments from labeling requirements under designated conditions if the labeling requirement applied only to retail packages in the first place.

"Appellants rely in large part on a case under the Food and Drugs Act of 1906, 34 Stat. 768, *United States* v. *Sixty-Five Casks Liquid Extracts*, 170 Fed. 449 (N. D. W. Va. 1909) affirmed on appeal by memorandum decision in *United States* v. *Knowlton Danderine Co.*, 175 Fed. 1022 (C. C. A. 4th, 1910). They contend (1) that the case was cited with approval in *Hipolite Egg Co.* v. *United States*, 220 U. S. 45 (1911), and (2) that it is squarely in point with the case at bar. The *Danderine* case was unsuccessfully relied on by the plaintiff in error in the *Hipolite Egg* case. The Supreme Court set forth that case as follows, pp. 52, 53: 'The articles involved in the first case were charged with having been misbranded and consisted of drugs in casks, which were shipped from Detroit, Michigan, to Wheeling, West Virginia, there to be received by the Knowlton Danderine Company in bulk in carload lots and manufactured into danderine, of which no sale was to be made until the casks should be emptied and the contents placed in properly marked bottles.

" 'It was contended that the articles, not having been shipped in the casks for the purpose of sale thus in bulk, but shipped to the owner from one State to another for the purpose of being bottled into small packages suitable for sale, and when so bottled to be labeled in compliance with the requirements of the act, were not transported for sale, and were therefore not subject to libel under § 10 of the act.

" 'The contention submitted to the court the construction of the statute. The court, however, based its decision upon the want of power in Congress to prohibit one from manufacturing a product in a State and removing it to another State "for the purpose of personal use and not sale, or for use in connection with the manufacture of other articles, to be legally branded when so manufactured;" and concluded independently, or as construing the statute, that the Danderine company, being the owner of the property, shipped it to itself and did not come within any of the prohibitions of the statute. The case was affirmed by the Circuit Court of Appeals, 175 Fed. 1022. The court, however, expressed no opinion as to the power of Congress. It decided that the facts did not exhibit a case within the purpose of the statute, saying: "No attempt to evade the law, either directly or indirectly or by subterfuges, has been shown, it appearing that the manufacturer had simply transferred from one point to another the product he was manufacturing for the purpose of completing the preparation of the same for the market. Under the circumstances disclosed in this case, having in mind the object of the Congress in enacting the law involved, we do not think the liquid extracts proceeded against should be forfeited. In reaching this conclusion we do not find it necessary to consider other questions discussed by counsel and referred to in the opinion of the court." '

"Additional facts not stated by the Supreme Court were that Parke, Davis & Co., under a contract with the Danderine Company, compounded the product in accordance with a formula, a trade secret owned by the Danderine Company, and caused it to be shipped to that company. Whether it was a part of the agreed statement of facts, or whether it was a conclusion from the terms of the contract, Parke, Davis & Co. were considered by the circuit court to be agents of the Danderine Company and not independent contractors in the manufacturing of the product. We cannot conclude the same, nor was it so argued to us at the hearing, as to the Arner Company here. In the facts before us, insofar as the manufacturing of the drug is concerned, Arner Company cannot be said to be mere agents. They compounded the drug as independent contractors and title passed at some time to Paul Case.

"As was mentioned above, the Supreme Court refused to sustain the plaintiff in error's position in the *Hipolite Egg* case, and the plaintiff in error there relied

on the *Knowlton Danderine* case. The facts in *Hipolite Egg Co.* v. *United States*, *supra*, p. 50, were these: the action was a libel under § 10 of the Act of 1906, 34 Stat. 768, '* * *' against fifty cans of preserved whole eggs, which had been prepared by the Hipolite Egg Company of St. Louis, Missouri.

"'The eggs before the shipment alleged in the libel were stored in a warehouse in St. Louis for about five months, during which time they were the property of Thomas & Clark, an Illinois corporation engaged in the bakery business at Peoria, Ill.

"'Thomas & Clark procured the shipment of the eggs to themselves at Peoria, and upon the receipt of them placed the shipment in their storeroom in their bakery factory along with other bakery supplies. The eggs were intended for baking purposes, and were not intended for sale in the original, unbroken packages or otherwise, and were not so sold. The Hipolite Egg Company appeared as claimant of the eggs, intervened, filed an answer, and defended the case, but did not enter into a stipulation to pay costs.

"'Upon the close of libellant's evidence, and again at the close of the case, counsel for the Egg Company moved the court to dismiss the libel on the ground that it appeared from the evidence that the court, as a Federal court, had no jurisdiction to proceed against or confiscate the eggs, because they were not shipped in interstate commerce for sale within the meaning of § 10 of the Food and Drugs Act, and for the further reason that the evidence showed that the shipment had passed out of interstate commerce before the seizure of the eggs, because it appeared that they had been delivered to Thomas & Clark and were not intended to be sold by them in the original packages or otherwise.'

"The decision of the Supreme Court affirming the decree of condemnation must be taken as in effect a disapproval of the doctrine of the *Danderine* case. As was said in *Strong, Cobb & Co.* v. *United States*, 103 F. (2d) 671, 673 (C. C. A. 6th, 1939): 'However, appellant maintains that under the doctrine of *United States* v. *Knowlton Danderine Co.*, 4 Cir., 175 F. 1022, there was in contemplation of law no shipment in interstate commerce under the Food and Drugs Act because the tablets were shipped in bulk, to be repackaged by the Scotch-Tone Company before retail distribution. The conclusive answer to appellant's contention is that the doctrine of the *Knowlton Danderine Co.* case has been in effect disapproved in *Hipolite Egg Co.* v. *United States*, 220 U. S. 45, 31 S. Ct. 364, 55 L. Ed. 364. In that case the Knowlton Danderine decision was relied on as supporting the proposition that Section 10 of the Food and Drugs Act, 21 U. S. C. A. § 14, does not apply to an article of food which has not been shipped for sale, but which has been shipped solely for use as raw material in the manufacture of some other product. The court, in discussing the proposition, states that the situations covered by the statute cannot be qualified "by the purpose of the owner to be a sale" and holds that the contention of the Egg Company is untenable.' See also *Philadelphia Pickling Co.* v. *United States*, 202 F. 150, 151–2, (C. C. A. 3rd, 1913).

"The appellant Arner Company argues that title to the drugs passed to Paul Case within the state of origin for transportation and that Arner Company acted merely as agent for Case in shipping the goods in interstate commerce, hence the shipment is not within the Act. Such argument cannot avail the appellants. The passing of title in the state of origin for transportation does not take the case out of the Act. *Hipolite Egg Co.* v. *United States*, *supra*; *United States* v. *Tucker*, U. S. D. C. S. D. Ohio, April 8, 1911 (reported in *Decisions of Courts In Cases Under The Federal Food and Drugs Act* by Mastin G. White and Otis H. Gates, at page 248).

"As was said in *Santa Cruz Fruit Packing Co. v. National Labor Relations Board*, 303 U. S. 453, 463 (1938): '. . . sales to purchasers in another State are not withdrawn from federal control because the goods are delivered f. o. b. at stated points within the State of origin for transportation. See *Savage* v. *Jones*, 225 U. S. 501, 520; *Texas & N. O. R. Co.* v. *Sabine Tram Co.*, 227 U. S. 111, 114, 122; *Pennsylvania R. Co.* v. *Clark Bros. Coal Mining Co.*, 238 U. S. 456, 465–468. A large part of the interstate commerce of the country is conducted upon that basis and the arrangements that are made between seller and purchaser with respect to the place of taking title to the commodity, or as to the payment of freight, where the actual movement is interstate, do not affect either the power of Congress or the jurisdiction of the agencies which Congress has established . . .' 'The Act is concerned not with the proprietory relation to a misbranded or an adulterated drug but with its distribution.' *United States* v. *Dotterweich*, 320 U. S. 277, 283 (1943).

"The appellants argue that although *Hipolite Egg Co.* v. *United States, supra,* and *Strong, Cobb & Co.* v. *United States, supra,* were cases holding bulk shipments within the earlier Act, those cases involved adulterated goods which, of course, would be harmful to the ultimate consumer. Since such consumer never will see the label on the bulk package, the argument runs, there is no protection to him in requiring such label and hence nothing in such a requirement facilitates the purposes of the Act.[2] The argument is based on the maxim that where the reason ceases (protection of consumer) the rule also ceases. The fallacy in this line of reasoning lies in a misconception of the functions of the label. In addition to advising the ultimate consumer, there are other purposes of a label: 'The label upon the unsold article is in the one case the evidence of the shipper that he has complied with the act of Congress, while in the other, by its misleading and false character, it furnishes the proof upon which the Federal authorities depend to reach and punish the shipper and to condemn the goods. If truly labeled within the meaning of the act his goods are immune from seizure by Federal authority; if the label is false or misleading within the terms of the law the goods may be seized and condemned. In other words the label is the means of vindication or the basis of punishment in determining the character of the interstate shipment dealt with by Congress.' *McDermott* v. *Wisconsin,* 228 U. S. 115, 132–133 (1913). If adulterated bulk shipments are within the purview of the act as established by the *Hipolite Egg* and *Strong, Cobb & Co.* cases, the requirement of labeling of bulk goods facilitates the detection and proof of such adulteration. Of course, enforcement of a labeling requirement could not be effective if the failure to meet the requirement were prosecuted only in the comparatively rare instances where the goods actually were adulterated.

"Another facet of the same argument is appellants' contention that since Paul Case supplied the formula for the drugs he knew what they were to contain and therefore any label indicating the contents would be superfluous. This argument overlooks the aforementioned functions of a label. If the drugs sent out by the Arner Company were of less strength than called for by the order, Paul Case might not detect this and might repack them in retail containers, misbranding them because the Arner Company had not properly filled his order, and the ultimate consumer would be getting a product which was adulterated within the meaning of the Act. If the bulk shipment were labeled, the Food and Drug administrators would be aided in detecting the adulteration since they could sample the bulk shipment and compare it with the label. In this way the administration of the Act would be facilitated. Adulteration could be detected in the early bulk stage before it ever got into retail channels.

"We turn now to a consideration of § 503 (a) which provides for regulations exempting bulk shipments from the labeling requirement:[3] 'Sec. 353(a). The Administrator is hereby directed to promulgate regulations exempting from any labeling or packaging requirement of this Act drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated

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[2] Since the regulations provided for by the Act exempt bulk goods from the labeling requirement on condition that certain information otherwise required on the label is set forth in an agreement, this argument would be more properly addressed to those regulations hereinafter considered.

[3] Sen. Rep. No. 493, 73rd Cong., 2d Sess., 1934, p. 9, accompanying S. 2800, one of the bills leading to enactment of the present law declared: 'Par. (c) authorizes the exemption from any labeling or packaging requirement of the bill articles which are, in accordance with the practice of the trade, processed, labeled, or repacked in substantial quantities at establishments other than those where they are originally processed or packed, on condition that the articles conform to the provisions of the bill at the time they leave the processing, labeling or repacking establishment. This exemption is necessary to avoid unwarranted interference with certain legitimate commercial operations, such as the canning of food at branch canneries and delivery to a central plant for labeling, or the bulk shipment of crude drugs for processing and repacking before distribution to consumers.'

In House Report No. 2139 (75th Cong., 3rd Sess., 1938) the following comment on section 405(2) of the bill in relation to exemption of labeling with respect to food appears (p. 6): "Section 405 authorizes exemptions from the labeling requirements of the act which are not provided by the present law but which have been permitted by administrative regulation. There is no necessity for labeling of any kind on most of the types of open containers of fresh fruits and fresh vegetables. In certain cases there is a very real need for the exemption of canned food and other food from labeling. For example, most of the salmon packed in Alaska is shipped unlabeled to Seattle, Portland, and San Francisco, and from these points distributed under appropriate label. The exemptions will apply only where the interests of consumers will not be jeopardized."

or misbranded under the provisions of this chapter upon the removal from such processing, labeling, or repacking establishment.' The pertinent regulation promulgated under this section provides: 'Regulation. [§ 2.107] (a) Except as provided by paragraphs (b) and (c) of this regulation, a shipment or other delivery of a drug or device which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling and packaging requirements of sections 501(b) and 502(b), (d), (e), (f), and (g) of the Act if—(1) The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such drug or device is to be processed, labeled, or repacked; or (2) in case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post-office addresses of such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such drug or device in such establishment as will insure, if such specifications are followed, that such drug or device will not be adulterated or misbranded within the meaning of the Act upon completion of such processing, labeling, or repacking. Such person and such operator shall each keep a copy of such agreement until all such shipment or delivery has been removed from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Agency who requests them.' [4]

"The appellants contend that the Administrator went beyond the statute in requiring a written agreement containing specifications. Their contention is that § 503(a) requires regulations flatly exempting such bulk shipments from the labeling provision and providing no safeguarding conditions to such exemption. To so construe the section would 'read(s) an exception to an important provision safeguarding the public welfare with a liberality which more appropriately belongs to enforcement of the central purpose of the Act'. *United States* v. *Dotterweich*, 320 U. S. 277 (1943). The Supreme Court thus clearly indicated in the *Dotterweich* case what must be our guide in construing the Act. As Mr. Justice Frankfurter said: 'The Food and Drugs Act of 1906 was an exertion by Congress of its power to keep impure and adulterated food and drugs out of the channels of commerce. By the Act of 1938, Congress extended the range of its control over illicit and noxious articles and stiffened the penalties for disobedience. The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words. See *Hipolite Egg Co.* v. *United States*, 220 U. S. 45, 57, and *McDermott* v. *Wisconsin*, 228 U. S. 115, 128. * * * Nothing is clearer than that the later legislation was designed to enlarge and stiffen the penal net and not to narrow and loosen it. This purpose was unequivocally avowed by the two committees which reported the bills to the Congress. The House Committee reported that the Act "seeks to set up effective provisions against abuses of consumer welfare growing out of inadequacies in the Food and Drugs Act of June 30, 1906". (H. Rep. No. 2139, 75th Cong., 3rd Sess., p. 1.) And the Senate Committee explicitly pointed out that the new legislation "must not weaken the existing laws", but on the contrary "it must strengthen and extend that law's protection of the consumer". (S. Rep. No. 152, 75th Cong., 1st Sess., p. 1).'

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[4] The remainder of this regulation provides:

"(b) An exemption of a shipment or other delivery of a drug or device under clause (1) of paragraph (a) of this regulation shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment, become void *ab initio* if the drug or device comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the Act when so removed. . . ."

"(d) An exemption of a shipment or other delivery of a drug or device under clause (2) of paragraph (a) of this regulation shall expire—

"(1) at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment if the drug or device comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the Act when so removed; or

"(2) upon the refusal by the operator of the establishment where such drug or device is to be processed, labeled, or repacked, to make available for inspection a copy of the agreement, as required by such clause."

"Section 503 (a) does not state the exemption. 'It authorizes the formulation of the exemption by regulations. Therefore, unless contrary to law, arbitrary, or unreasonable, the terms of the exemption can be prescribed in the discretion of the administration'. See Hoge: *An Appraisal of the New Drug and Cosmetic Legislation*, 6 Law and Contemporary Problems 116. Had Congress intended an outright exemption of bulk shipments from the labeling requirement without restrictive terms of any sort, there would have been no need for it to provide for regulations formulating the exemption; the law would have simply stated the exemption. The agreement containing specifications for the labeling of the drugs as provided in regulation (a) (2) serves the same purposes of facilitating the enforcement of the Act as was indicated by the Supreme Court in *McDermott* v. *Wisconsin*, *supra*, to be the purpose served by a label on a retail article before the article is sold. Applied to a situation like the case at bar it would aid in the detection and proof of adulteration in the shipment from the manufacturer to the proprietor of the formula. *Cf. Strong, Cobb & Co., Inc.* v. *United States*, *supra*. There is no hindrance to honest business in this requirement. The instrument [5] which is here purported to be such an agreement is neither signed by the shipper nor does it contain any specifications for the labeling as required by the regulation (a) (2). Obviously such an instrument does not serve the useful function indicated above and was intended for some purpose entirely foreign to the regulation.

"Regulation (a) (1) is not applicable to this case. It pertains to a case where the repacker and the person shipping the article to be repacked are one and the same person with plants in different states. See Toulmin, *Law of Food, Drugs and Cosmetics* (1942) p. 322, § 173. There is no danger in such a case of the repacker unwittingly passing on adulterated drugs to the ultimate consumer. The regulation does not exempt a repacker who introduces the goods into commerce through an 'agent' designated for that purpose, which 'agent' was the vendor of the goods. This 'agency' of the Arner Company to ship the goods can no more bring the appellants within regulation (a) (1) than can it avoid the scope of interstate commerce as indicated by the cases cited in the earlier part of this opinion.

The decree of the District Court is affirmed.

The Arner Co., Inc., subsequently filed with the United States Supreme Court an application for a writ of certiorari, and on October 9, 1944, the application was denied.

1158. Misbranding of Fruitola, Traxo, and Abbott Bros. Compound. U. S. v. 8 Dozen Packages of Fruitola, 3½ Dozen Packages of Traxo, and 8 Packages of Abbott Bros. Compound. Decree of condemnation and destruction. (F. D. C. Nos. 6541 to 6543, incl. Sample Nos. 71321–E to 71323–E, incl.)

On December 18, 1941, the United States attorney for the Eastern District of Missouri filed libels against 8 dozen packages of Fruitola, 3½ dozen packages of Traxo, and 8 packages of Abbott Bros. Compound at St. Louis, Mo., alleging that the articles had been shipped on or about April 21 and September 29, 1941, from Monticello, Ill., by the Pinus Medicine Co.; and charging that they were misbranded.

Examination of the Fruitola disclosed that each package contained 4 powders in blue paper, 2 powders in white paper, and a bottle of a liquid. The powder in the blue paper consisted of sodium bicarbonate and Rochelle salt; the powder in the white paper consisted of tartaric acid; and the liquid in the bottle consisted essentially of olive oil and anise oil. The article was alleged to be misbranded because of false and misleading statements appearing in its labeling which

[5] "Paul Case,
Sole Distributor Case Combination New Improved Method
for 'Rheumatic' Pains,
33 Hamilton St., Brockton, Mass.
April 28, 1939, Brockton, Massachusettts.

To The Arner Company, Inc., Pharmaceutical Chemists, Buffalo, New York.

I, the undersigned, Paul Case, whose address is 33 Hamilton St., Brockton, State of Massachusetts, hereby guarantee the Arner Company, Inc., of Buffalo, New York, that each shipment or other delivery hereinafter made of the drugs known or designed as my formula No. 1 and formula No. 2 is not adulterated or misbranded, as of the date of such shipment or delivery, within the meaning of the Federal Food, Drug and Cosmetics Act, and is not an article which may not under the provisions of sec. 505 of the act be introduced into commerce.

(signed) PAUL CASE, Owner."

created the impression that it would promote the proper elimination of waste in the intestinal tract and regulate the flow of bile; that the article designated as Traxo was a tonic and a stimulant to the digestive tract and its nerve system and, when used in conjunction with Fruitola, would increase the efficacy of Fruitola; and that the preparation designated as Abbott Bros. Compound was efficacious in the treatment of muscular pains in limbs, sides, and back, rheumatism, neuritis, arthritis, sciatica, lumbago, and gout. It was alleged to be misbranded further (1) in that the name "Fruitola" and the reference to "fruit oils," appearing in the labeling, were false and misleading since they created the impression that the ingredients of the article were derived from fruits, whereas the ingredients of the article were not derived from fruits as commonly understood but consisted of sodium bicarbonate, Rochelle salt, tartaric acid, olive oil, and anise oil; and (2) in that the required statements of the active ingredients and of the quantity of contents of the article did not appear in its labeling in such terms as to render them likely to be understood by the ordinary individual under customary conditions of purchase and use, since the declaration of the active ingredients and the statement of the quantity of the contents were not set forth in a manner that made it clear that the carton contained two different preparations, one of which the manufacturer designated as "fruit oils" and the other as "compound effervescent powder."

Examination of the Traxo disclosed that it consisted essentially of alcohol, water, and extracts of plant materials including emodin, podophyllin, and strychnine. It was alleged to be misbranded because of false and misleading statements appearing in its labeling which created the impression that the article was a tonic and a stimulant to the digestive tract and its nerve system; that the preparation designated as Fruitola would increase the efficacy of Traxo; and that the preparation designated as Abbott Bros. Compound was efficacious in the treatment of muscular pains in the limbs, sides, and back, rheumatism, neuritis, arthritis, sciatica, lumbago, and gout.

Examination of Abbott Bros. Compound disclosed that it consisted essentially of water, alcohol, sodium salicylate, sodium phosphate, potassium nitrate, extracts of plant materials, and flavoring materials. It was alleged to be misbranded because of false and misleading statements appearing in its labeling which created the impression that it was a treatment for muscular aches and pains in the limbs, sides, and back; that Fruitola would promote the proper elimination of waste in the intestinal tract and regulate the flow of bile; and that Traxo was a tonic and a stimulant to the digestive tract and its nerve system. It was alleged to be misbranded further in that the article, when used as directed, would act as a laxative, and its labeling failed to warn the user that it should not be taken when suffering from nausea, vomiting, abdominal pains, or other symptoms of appendicitis, and that frequent or continued use of a laxative may result in dependence on a laxative.

On March 16, 1943, the sole intervenor having withdrawn its claim and answer, judgments of condemnation were entered and the products were ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

1159. Adulteration of Hart's Compound Asthma Medicine. U. S. v. 86 Bottles and 138 Bottles of Hart's Compound Asthma Medicine (and 17 other seizure actions against the same product). Default decrees of condemnation and destruction. (F. D. C. Nos. 10252, 10312, 10356, 10678, 10679, 10692, 10720 to 10722, incl., 10799, 10955, 10989, 10990, 10994, 10998, 11121, 12080 12115. Sample Nos. 8311-F, 11260-F, 16099-F, 16100-F, 21906-F, 21907-F, 21910-F, 21948-F, 22086-F, 22087-F, 34240-F, 35534-F, 36457-F, 38751-F, 48206-F to 48208-F, incl., 48232-F, 48233-F, 48240-F, 50336-F to 50338-F, incl., 51393-F to 51395-F, incl., 51602-F, 58937-F, 58938-F, 58944-F, 58945-F.)

Between July 15, 1943, and March 30, 1944, the United States attorneys for the Western District of Pennsylvania, the Northern Districts of California, Indiana, West Virginia, and Ohio, the District of Minnesota, the District of Utah, the District of Massachusetts, the District of Colorado, the Western District of North Carolina, and the District of Maryland filed libels against the following quantities of the above-named product, packed in containers of 2-fluid-ounce, 4-fluid-ounce, and 6-fluid-ounce sizes: 224 bottles at Uniontown, Pa., 117 bottles at San Francisco, Calif., 73 bottles at South Bend, Ind., 21 bottles at Minneapolis, Minn., 123 bottles and 59 packages at Cleveland, Ohio, 70 packages at Wheeling, W. Va., 85 packages and 71 bottles at Pittsburgh, Pa., 71 packages

at Ogden, Utah, 142 packages at Boston, Mass., 46 packages at Denver, Colo., 59 packages at Charlotte, N. C., and 108 bottles at Baltimore, Md.; alleging that the article, which had been consigned by the Hart's Asthma Medicine Company, had been shipped from Buffalo, N. Y., from on or about November 19, 1941, to February 17, 1944; and charging that it was adulterated. On May 18, 1944, the libel against the lot at Baltimore was amended to cover the seizure of an additional amount of the article.

The article was alleged to be adulterated in that it consisted of a filthy substance, a mold-containing liquid.

Between September 14, 1943, and May 19, 1944, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

1160. Adulteration and misbranding of damaged drugs. U. S. v. 1,300 Cases of Petrolagar, 785 Cartons of Hematinic Plastules, and 490 Cartons of Amphojel Keomagma. Default decree of condemnation and destruction. (F. D. C. No. 10777. Sample No. 52831–F.)

On September 17, 1943, the United States attorney for the Eastern District of Virginia filed a libel against the above-mentioned products at Portsmouth,, Va., alleging that the articles had been shipped on or about September 30, 1942, from Baltimore, Md.; and charging that they were adulterated and misbranded.

The articles became damaged by bilge water en route from Baltimore to Portsmouth, where the vessel put in for repairs. The articles were there unloaded and placed in a warehouse.

The articles were alleged to be adulterated in that they had been held under insanitary conditions whereby they may have become contaminated with filth. They were alleged to be misbranded in that the information required by law to appear on the label or labeling was not prominently placed thereon with such conspicuousness as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, since the labeling in part had been damaged and rendered illegible, or had been entirely detached from the packages upon which it had originally been placed.

On February 1, 1944, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

1161. Adulteration of miscellaneous crude drugs. U. S. v. 125 Pounds of Uva Ursi Leaves, 100 Pounds of Marjoram, 100 Pounds of Coriander Seed, 20 Pounds of Poke Root, 75 Pounds of Sarsaparilla Root, and 75 Pounds of Ground Ginger Root. Default decree of condemnation and destruction. (F. D. C. No. 10177. Sample Nos. 20500–F, 20723–F, 20727–F to 20730–F, incl.)

These products were stored, after shipment, in rooms which were overrun with rats and exceedingly filthy. Examination disclosed that the uva ursi leaves were contaminated with rodent excreta pellets and rodent hairs; that the marjoram was contaminated with rodent excreta pellets; that the coriander seed contained weevils and rodent hairs and that a material proportion was worm-eaten; that the poke root was contaminated with rodent excreta pellets and rodent hairs; that the sarsaparilla root was contaminated with rodent excreta pellets; and that the ground ginger root contained a large number of dead weevils.

On July 2, 1943, the United States attorney for the District of Massachusetts filed a libel against the above-mentioned quantities of crude drugs at Boston, Mass., alleging that the articles had been shipped from New York, N. Y., and Jersey City, N. J., within the period from on or about January 16, 1941, to December 9, 1942, and that they were in the possession of the G. S. Cheney Co., Inc.; and charging that they were adulterated.

The articles were alleged to be adulterated in that they consisted in whole or in part of filthy substances; and in that they had been held under insanitary conditions whereby they may have been contaminated with filth.

The articles, with the exception of the uva ursi leaves and the poke root, were also alleged to be adulterated under the provisions of the law applicable to foods, as reported in the notices of judgment on foods.

On August 2, 1943, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

1162. Adulteration of senna. U. S. v. 639 Bags of Senna. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 10913. Sample No. 34243–F.)

On October 11, 1943, the United States attorney for the Northern District of West Virginia filed a libel against 639 bags, each containing approximately 300

pounds, of senna at Wheeling, W. Va., alleging that the article had been shipped from New York, N. Y., from on or about October 6 to 20, 1942, and that it was in the possession of Sterling Drug, Inc.; and charging that it was adulterated.

The article was alleged to be adulterated in that it consisted in whole or in part of a filthy substance by reason of the presence of webbing, adult insects, insect larvae, insect fragments and capsules, and large quantities of insect excreta; and in that it had been held under insanitary conditions whereby it had been contaminated with filth.

It was alleged to be further adulterated in that it purported to be and was represented as a drug, senna, the name of which is recognized in an official compendium, the United States Pharmacopeia, but its quality and purity fell below the standard set forth in that compendium since it was not substantially free from insects, extraneous animal matter and animal excreta, but contained filth of the nature described above.

On January 7, 1944, the Sterling Drug, Inc., Wheeling, W. Va., claimant, having admitted that the product was adulterated as charged in the libel, judgment of condemnation was entered and the product was ordered released under bond to be brought into compliance with the law under the supervision of an employee designated by the Federal Security Administrator.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

1163. Adulteration and misbranding of Phenolix Elixir Phenobarbital. U. S. v. Wayne Pharmacal Supply Co. Plea of nolo contendere. Fine, $50 and costs. (F. D. C. No. 9687. Sample No. 584–F.)

On August 27, 1943, the United States attorney for the Northern District of Indiana filed an information against the Wayne Pharmacal Supply Co., a corporation, Fort Wayne, Ind., alleging shipment of a quantity of the above-named product on or about November 10, 1942, from the State of Indiana into the State of Michigan.

The article was alleged to be adulterated in that it purported to be a drug, the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality or purity fell below the standard set forth therein since the compendium provides that elixir of phenobarbital shall be a clear elixir and shall contain not less than 12 percent of alcohol and 450 cc. of glycerin per 1,000 cc., whereas the article was not a clear elixir, but was a liquid containing a large amount of precipitated, crystallized phenobarbital, and it contained not more than 0.15 percent of alcohol and not more than 26 cc. of glycerin per 1,000 cc.

It was alleged to be misbranded in that it was for use by man and it contained phenobarbital, a derivative of barbituric acid, a hypnotic substance, which derivative has been, after investigation, found to be, and by regulations has been designated as, habit-forming, and the label of the article did not bear the name and quantity or proportion of such derivative and, in juxtaposition therewith, the statement "Warning—May be habit forming."

On January 6, 1944, the defendant having entered a plea of nolo contendere, the court imposed a fine of $25 on each of 2 counts, plus costs.

1164. Misbranding of oxygen-carbon dioxide mixture. U. S. v. Stuart Oxygen Co. Plea of nolo contendere. Fine, $300. (F. D. C. No. 10603. Sample Nos. 13894–F, 14167–F, 39332–F.)

On December 16, 1943, the United States attorney for the Southern District of California filed an information against the Stuart Oxygen Co., a corporation, Los Angeles, Calif., alleging shipment of quantities of the above-named product from the State of California into the State of Arizona on or about July 14, 1942, and April 7 and May 11, 1943.

The article was alleged to be misbranded in that the statements appearing on the labeling of one portion of the article, which represented and suggested that it contained not less than 5 percent of carbon dioxide, and on the labeling of the remainder, which represented and suggested that it contained not less than 10 percent of carbon dioxide, were false and misleading since the article contained, in the case of the former, not more than 3.5 percent of carbon dioxide, and, in the case of the latter, not more than 7.4 percent of carbon dioxide.

On February 14, 1944, the defendant having entered a plea of nolo contendere, the court imposed a fine of $100 on each of 3 counts.

*See also Nos. 1151–1153, 1162.

1165. Adulteration and misbranding of sulfanilamide capsules. U. S. v. Peerless Serum Co. Plea of guilty. Fine, $100 and costs. (F. D. C. No. 10615. Sample No. 5687–F.)

On January 24, 1944, the United States attorney for the District of Kansas filed an information against the Peerless Serum Co., a corporation, Kansas City, Kans., alleging shipment of a quantity of sulfanilamide capsules from the State of Kansas into the State of Arkansas on or about April 30, 1943.

The article was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess since it was represented to contain 240 grains of sulfanilamide per capsule, whereas it contained 306.17 grains of sulfanilamide per capsule.

It was alleged to be misbranded in that the statement on its label, "Sulfanilamide * * * 240 grs.," was false and misleading.

On January 31, 1944, the defendant having entered a plea of guilty, the court imposed a fine of $100 and costs.

1166. Adulteration and misbranding of tincture of iodine and peroxide of hydrogen, and misbranding of syrup of cocillana compound. U. S. v. Boston Drug & Chemical Co. Plea of guilty. Fine, $100. (F. D. C. No. 10599. Sample Nos. 19226–F, 19600–F, 20429–F.)

On January 14, 1944, the United States attorney for the District of Massachusetts filed an information against the Boston Drug & Chemical Co., a corporation, Boston, Mass., alleging shipment from the State of Massachusetts into the State of Maine of a quantity of tincture of iodine, on or about December 23, 1942, and into the State of Rhode Island of a quantity of hydrogen of peroxide and syrup of cocillana compound, on or about December 2, 1942, and April 2, 1943, respectively.

The tincture of iodine was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in an official compendium, the United States Pharmacopoeia, but its strength differed from or its quality fell below the standard set forth therein since the Pharmacopoeia provides that tincture of iodine shall contain, in each 100 cc., not less than 6.8 grams of iodine and not less than 4.7 grams of potassium iodide, whereas the article contained iodine in amounts varying from 3.67 grams to 4.16 grams per 100 cc., and potassium iodide in amounts varying from 3.19 grams to 3.49 grams per 100 cc.; and its difference in strength and quality from the standard set forth in the compendium was not plainly stated on the label. The article was alleged to be misbranded in that the statement "Tincture Iodine U. S. P.," borne on its label, was false and misleading.

The hydrogen of peroxide was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in an official compendium, the United States Pharmacopoeia, and its strength differed from and its quality fell below the standard set forth therein since the Pharmacopoeia provides that an article recognized under the name solution of hydrogen peroxide shall contain, in each 100 cc., not less than 2.5 grams of hydrogen peroxide, whereas the article contained hydrogen peroxide in amounts varying from 1.43 grams to 1.57 grams per 100 cc.; and its difference in strength and quality from the standard set forth in the compendium was not plainly stated on the label. It was alleged to be misbranded in that the statements on its label which represented and suggested that it consisted of solution of hydrogen peroxide conforming with the specifications of the United States Pharmacopoeia; that it contained 3 percent of hydrogen peroxide; and that it contained one-fifth grain of acetanilid per fluid ounce were false and misleading since the article did not consist of solution of hydrogen peroxide conforming with the specifications of the Pharmacopoeia, and it contained no acetanilid and less than 3 percent of hydrogen peroxide.

Analysis of the syrup of cocillana compound disclosed that it consisted essentially of plant extractives, alcohol, sugar, and water. The article was alleged to be misbranded in that the statement appearing on its labels, "For Coughs, Colds, and Irritated Conditions of the Throat," was false and misleading since the article would not be efficacious in the cure, mitigation, treatment, or prevention of coughs, colds, or irritated conditions of the throat.

On January 25, 1944, a plea of guilty having been entered on behalf of the defendant, the court imposed a fine of $100.

1167. Adulteration and misbranding of solution or tincture of iodine. U. S. v. 276 Packages and 186 Packages of Solution or Tincture of Iodine. Default decree of condemnation and destruction. (F. D. C. No. 10972. Sample Nos. 29677–F, 29678–F.)

On October 22, 1943, the United States attorney for the Northern District of California filed a libel against 462 packages of the above-described product at San Francisco, Calif., alleging that the article had been shipped from Chicago, Ill., by the C. A. Mosso Co. on or about March 19, 1942, and April 29, 1943; and charging that it was adulterated and misbranded. The article was labeled in part: (Carton) "Mult-Aply ½ Strength Tincture Iodine," (vial) "Mult-Aply Solution of Iodine 3½%."

Examination of the article showed that it contained 2.2 grams of iodine and 3.63 grams of potassium iodide in each cubic centimeter, and approximately 41 percent of alcohol. The United States Pharmacopoeia provides that tincture of iodine shall contain, in each 100 cc., not less than 6.8 grams of iodine and not less than 4.7 grams of potassium iodide, and shall contain from 83 to 88 percent of alcohol by volume; and that solution of iodine shall contain, in each 100 cc., not more than 2.2 grams of iodine and not more than 2.6 grams of sodium iodide. Solution of iodine does not contain alcohol.

The article was alleged to be adulterated in that it purported to be and was represented as tincture of iodine and solution of iodine, names of drugs which are recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from the standard set forth in that compendium.

It was alleged to be misbranded in that the statements appearing upon its labeling, (carton) "½ Strength Tincture Iodine," and (vial label) "Solution of Iodine 3½%," were false and misleading as applied to a product which was neither one-half strength tincture of iodine nor solution of iodine.

On March 25, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1168. Adulteration and misbranding of mild tincture of iodine. U. S. v. 1,068 Bottles of Mild Tincture of Iodine. Default decree of condemnation and destruction. (F. D. C. No. 10685. Sample No. 11546–F.)

Examination of samples of this product disclosed that it contained 1.64 grams of iodine in each 100 cc., whereas the United States Pharmacopoeia provides that mild tincture of iodine shall contain 1.8 grams of iodine per 100 cc.

On September 8, 1943, the United States attorney for the Northern District of California filed a libel against 1,068 bottles of mild tincture of iodine at San Francisco, Calif., alleging that the article had been shipped on or about October 11, 1942, from St. Louis, Mo., by the United Drug Co.; and charging that it was adulterated and misbranded. The article was labeled in part: "Puretest Mild Tincture Iodine U. S. P."

The article was alleged to be adulterated in that it was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its strength differed from the standard set forth in that compendium, and its difference in strength from the standard was not stated on its label.

It was alleged to be misbranded in that the statement, "Mild Tincture Iodine U. S. P.," appearing on its label, was false and misleading since the article did not comply with the U. S. P. standard.

On October 18, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1169. Adulteration and misbranding of digitalis tablets. U. S. v. 10 Bottles of Digitalis Tablets. Default decree of condemnation and destruction. (F. D. C. No. 10920. Sample No. 53173–F.)

On October 9, 1943, the United States attorney for the District of Maryland filed a libel against 10 100-tablet bottles of the above-named product at Baltimore, Md., alleging that the article had been shipped on or about May 13, 1943, from Richmond, Va., by Charles C. Haskell & Co.; and charging that it was adulterated and misbranded. The article was labeled in part: "Digitalis * * * Whole Leaf Tablets."

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from the stand-

ard set forth therein since it contained an amount of powdered digitalis corresponding in potency to less than 95 percent of the labeled amount, the minimum permitted by the Pharmacopoeia; and its difference in strength from the standard was not plainly stated on its label.

The article was alleged to be misbranded in that the statement on its label, "Each tablet represents 1½ grains of digitalis leaf," was false and misleading since each tablet represented not more than 0.87 grain of digitalis leaf.

On January 12, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1170. Adulteration and misbranding of gauze bandages. U. S. v. Marsales Co., Inc. Plea of nolo contendere. Fine, $3,500. (F. D. C. No. 10634. Sample Nos. 6769-F, 6775-F, 37578-F, 37579-F, 45766-F, 45785-F, 45786-F, 45822-F.)

On or about January 7, 1944, the United States attorney for the District of Connecticut filed an information against the Marsales Co., Inc., Niantic, Conn., alleging shipment from the State of Connecticut into the States of Missouri and Virginia, from on or about October 8, 1942, to April 22, 1943, of quantities of gauze bandages which were adulterated and misbranded. The article was labeled in part: "Marco * * * Gauze Bandage," or "Bandage Gauze Roller Plain."

A portion of the article was alleged to be adulterated in that it purported to be and was represented as gauze bandage, a drug the name of which is recognized in an official compendium, the United States Pharmacopoeia, but its quality or purity fell below the standard set forth therein since the Pharmacopoeia provides that gauze bandage must be sterile, whereas the article was not sterile but was contaminated with aerobic and anaerobic gram-positive, spore-bearing bacilli; and its difference in quality or purity from the standard set forth in the compendium was not plainly stated on its label. The remainder of the article was alleged to be adulterated in that its purity or quality fell below that which it purported and was represented to possess since it purported to be and was represented as sterile, whereas it was not sterile but was contaminated with bacilli of the nature described above.

The article was alleged to be misbranded in that the statement "Sterilized," borne on the cartons, was false and misleading since the article was not sterile.

On January 17, 1944, the charges in the information of adulteration and misbranding were combined in 1 count on each shipment, making a total of 7 counts, and on the same date the defendant entered a plea of nolo contendere and the court imposed a fine of $500 on each of the 7 counts.

1171. Adulteration of cascara sagrada bark. U. S. v. 52 Bags of Cascara Sagrada Bark. Default decree of condemnation and destruction. (F. D. C. No. 10696. Sample No. 11551-F.)

On September 7, 1943, the United States attorney for the Northern District of California filed a libel against 52 bags of cascara sagrada bark at San Francisco, Calif., alleging that the article had been shipped on or about April 9, May 3, and July 23, 1943, from Aberdeen, Wash., by J. H. Mathisen; and charging that it was adulterated.

The article was alleged to be adulterated in that it purported to be and was represented as a drug, cascara sagrada, the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth therein since it was not free from mold and showed substantial discoloration and deterioration.

On January 25, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1172. Adulteration of ampuls of calcium gluconate. U. S. v. 200 Ampuls of Calcium Gluconate. Default decree of condemnation and destruction. (F. D. C. No. 11195. Sample No. 3938-F.)

On December 8, 1943, the United States attorney for the District of Kansas filed a libel against 200 ampuls of calcium gluconate at Wichita, Kans., alleging that the article had been shipped in interstate commerce on or about August 31, 1943, by Henry G. Haist & Co., from Kansas City, Mo.; and charging that it was adulterated.

The article was alleged to be adulterated in that it purported to be and was represented as calcium gluconate injection, a drug the name of which is recognized in the United States Pharmacopoeia, and its quality and purity fell below the standard set forth therein since the Pharmacopoeia provides that injections

must be clear and free of any turbidity or undissolved material which can be detected readily when examined by the method described in the Pharmacopoeia, whereas the article was found to contain undissolved material when so examined.

On December 10, 1943, the consignee of the product having admitted the material allegations of the libel, judgment of condemnation was entered and the product was ordered destroyed.

1173. Adulteration of sodium cacodylate. U. S. v. 2 Packages of Sodium Cacodylate. Default decree of condemnation and destruction. (F. D. C. No. 11133. Sample Nos. 57429–F, 57430–F.)

On November 18, 1943, the United States attorney for the Southern District of New York filed a libel against 2 10-pound packages of sodium cacodylate at New York, N. Y., alleging that the article had been shipped to Santiago, Chile, on or about August 18, 1943, and upon arrival there was found to be adulterated; and that it was returned to the United States, entering the port of New York on October 22, 1943.

The article was alleged to be adulterated in that it purported to be and was represented as sodium cacodylate, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from and its quality and purity fell below the standard set forth in the compendium since it is provided therein that sodium cacodylate shall contain not less than 72 percent of $Na(CH_3)_2AsO_2$, and that 1 gram of sodium cacodylate shall show no more chloride than corresponds to 0.3 cc. of fiftieth-normal hydrochloric acid, whereas the article contained not more than 64.3 percent of $Na(CH_3)_2ASO_2$, and, in addition, a portion of the article contained twice as much chloride as was permitted by the United States Pharmacopoeia.

On December 28, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1174. Adulteration of tartaric acid crystals. U. S. v. 22 Bottles of Tartaric Acid Crystals. Default decree of condemnation and destruction. (F. D. C. No. 11137. Sample No. 52926–F.)

On November 17, 1943, the United States attorney for the District of Maryland filed a libel against 22 bottles, each containing 1 pound, of tartaric acid crystals at Perry Point, Md., alleging that the article, which had been consigned by the Brocker Chemical Co., had been shipped from Morganville, N. J., on or about September 1, 1943; and charging that it was adulterated.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth in the compendium since the article contained foreign material such as wood splinters, insoluble, blue, glass-like material, and a few fragments of insects and hair, substances foreign to tartaric acid.

On December 20, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1175. Adulteration of triple distilled water. U. S. v. 460 Ampuls of Triple Distilled Water. Default decree of condemnation and destruction. (F. D. C. No. 11005. Sample No. 48842–F.)

On October 25, 1943, the United States attorney for the Eastern District of Kentucky filed a libel against 460 ampuls, 10 cc. size, of triple distilled water at Bellevue, Ky., alleging that the article had been shipped on or about September 20, 1943, from the Diarsenol Co., Inc., Buffalo, N. Y.; and charging that it was adulterated.

The article was alleged to be adulterated in that it purported to be a drug, ampuls of redistilled water, the name of which is recognized in the National Formulary VII, an official compendium, but its quality and purity fell below the standard set forth therein since it was contaminated with undissolved material.

On November 20, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1176. Adulteration of phenol red (phenolsulfonphthalein). U. S. v. 250 Bottles of Phenol Red (Phenolsulfonphthalein). Default decree of condemnation and destruction. (F. D. C. No. 10744. Sample No. 1435–F.)

On September 11, 1943, the United States attorney for the Northern District of New York filed a libel against 250 bottles, each containing 5 grams, of the above-named article at Binghamton, N. Y., alleging that the article had been

shipped on or about August 18, 1943, by the Paul-Lewis Laboratories, Inc., from Milwaukee, Wis.; and charging that it was adulterated.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the standard set forth therein since it yielded more ash and contained more insoluble substances than the maximum permitted by the compendium.

On December 3, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1177. Adulteration of prophylactics. U. S. v. 300 Gross of Rubber Prophylactics. Consent decree ordering the release of the product under bond. Subsequent decree entered ordering that the product be destroyed. (F. D. C. No. 10738. Sample No. 48212–F.)

On September 13, 1943, the United States attorney for the Northern District of Ohio filed a libel against 300 gross of rubber prophylactics at Cleveland, Ohio, alleging that the article had been shipped on or about August 20, 1943, by Hardy Newman & Co., Detroit, Mich.; and charging that it was adulterated. The article was labeled in part: "Modern-Tex Mfg. for Modern Distr. Co. Detroit, Mich."

Samples taken from the shipment were from 40 to 60 percent defective since that proportion was found to contain holes.

The article was alleged to be adulterated in that its quality fell below that which it purported to possess.

The Trutex Products, Inc., Cleveland, Ohio, claimant, filed an answer admitting interstate shipment, and admitting that a portion of the product might contain holes, but denying that from 40 to 60 percent were defective as alleged. The answer also averred that the claimant had originally shipped the product to Hardy Newman & Co., and that, upon discovery that a small portion might be defective, had ordered the goods returned to the claimant at Cleveland, Ohio, for the purpose of reinspection in order to bring them into compliance with the law; and that the product had been shipped as ordered by the claimant.

On October 19, 1943, the court having made its finding that the allegations admitted by the claimant were true and that the allegations contained in the claimant's answer with respect to the article were true, but that a portion of the product might be defective and adulterated, judgment was entered ordering that the product be released under bond to be brought into compliance with the law under the supervision of the Food and Drug Administration. On November 23, 1943, the product having been found to be so defective that it should be destroyed, a decree was entered ordering its destruction.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

DRUGS FOR HUMAN USE

1178. Misbranding of Floritone. U. S. v. Frank Tibbetts and Nancy Tibbetts (Vitolectic Food Co.). Pleas of guilty. Fines of $250 against each defendant. (F. D. C. No. 10630. Sample No. 19222–F.)

On February 8, 1944, the United States attorney for the District of Rhode Island filed an information against Frank Tibbetts and Nancy Tibbetts, the latter owning and operating a business under the firm name of Vitolectic Food Co., Providence, R. I., alleging shipment on or about April 12, 1943, from the State of Rhode Island into the State of Massachusetts of a quantity of Floritone.

Analysis disclosed that the article consisted essentially of whey, dextrin, and sugars such as glucose and milk sugar.

It was alleged to be misbranded because of false and misleading statements in its labeling which represented and suggested that the article, when used in accordance with the suggestions for use on the label, would be efficacious in increasing the body weight and in causing a reduction in body weight; and that it would be efficacious in the cure, mitigation, treatment, or prevention of diarrhea and toxemia.

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

On February 10, 1944, the defendants entered pleas of guilty and the court fined each defendant $125 on each of the 2 counts, a total fine of $250 with respect to each defendant.

*See also Nos. 1151–1156, 1158, 1164–1170.

1179. Misbranding of Dr. Corley's Alkaline Broth and Dr. Corley's Laxx. U. S. v. Dr. Buren L. Corley (Dr. Corley's Products). Plea of guilty. Fine, $450. (F. D. C. No. 10540. Sample Nos. 12857–F to 12859–F, incl., 12861–F.)

On September 16, 1943, the United States attorney for the Northern District of California filed an information against Dr. Buren L. Corley, trading as Dr. Corley's Products, San Francisco, Calif., alleging shipment from the State of California into the State of Oregon of a quantity of the above-named products on or about July 7, 1942, and of a quantity of Dr. Corley's Laxx on or about September 12, 1942.

Analysis of Dr. Corley's Alkaline Broth disclosed that the article consisted essentially of plant material including kelp and celery, meat extractive, and sodium chloride; and analysis of another drug, Dr. Corley's Garlic Tablets, showed that it consisted essentially of ground parsley, ground garlic, and probably ground onions, and that it was coated with calcium carbonate and sugar. The Alkaline Broth was alleged to be misbranded because of false and misleading statements appearing in its labeling which represented and suggested that the article would be efficacious as a blood alkalizer and would neutralize or combat body acids, clear acid from the blood, and alkalize the system; that it would be efficacious in the treatment of acid indigestion, anemia, asthma, auto-intoxication, biliousness, colitis, colds, constipation, catarrh, excess perspiration, food disagreements, gas-bloat, general low vitality, gall bladder trouble, high blood pressure, hay fever, heartburn, headaches, liver trouble, muscular aches and pains, nervous indigestion, overweight, poor appetite, rheumatism, skin eruptions, sinus trouble, sour stomach, gastritis, and low blood pressure; that another drug, Dr. Corley's Laxx, would be efficacious to cleanse the intestines thoroughly, like a soft, smooth sponge; and that another drug, Dr. Corley's Garlic Tablets, would be efficacious in the treatment of inflammation of the intestines.

Analysis of Dr. Corley's Laxx disclosed that the article consisted essentially of karaya gum, whole psyllium seed, anise seed, senna leaf fragments, a small proportion of peppermint leaf fragments, a trace of buckthorn bark, and unidentified seeds, stems, and woody material.

A portion of the Laxx was alleged to be misbranded because of false and misleading statements appearing in its labeling which represented and suggested that it would be efficacious to cleanse the intestines thoroughly like a soft, smooth sponge; that it would cure constipation and relieve sluggish intestinal conditions; that it would be efficacious in the cure, mitigation, treatment, or prevention of acid indigestion, anemia, asthma, auto-intoxication, biliousness, colitis, colds, catarrh, excess perspiration, food disagreements, gas-bloat, general low vitality, gall bladder trouble, high blood pressure, hay fever, heartburn, headaches, liver trouble, muscular aches and pains, nervous indigestion, overweight, poor appetite, rheumatism, skin eruptions, sinus trouble, sour stomach, gastritis, and low blood pressure; that another drug, Dr. Corley's Alkaline Broth, would be efficacious as a blood alkalizer and would neutralize or combat body acids, clear acid from the blood and alkalize the system; and that another drug, Dr. Corley's Garlic Tablets, would be efficacious in the treatment of inflammation of the intestines.

The remainder of the Laxx was alleged to be misbranded because of false and misleading statements in its labeling which represented and suggested that it would be efficacious as a cure for constipation and for relieving sluggish intestinal conditions; that it would cleanse the intestines thoroughly, like a soft, smooth sponge; that it would be an efficacious treatment for colitis; that it would assure one of eating and sleeping well; that it would help overcome chronic sluggish conditions of the liver and bowels, help in combatting stubborn cases of intestinal irritation, sweep and cleanse the stomach and intestines, and remove poisonous waste materials; that it would be efficacious in the treatment of asthma, acid indigestion, acne, biliousness, colds, catarrh, excess perspiration, food disagreements causing gas and bloat, general low vitality, gas, headaches, hay fever, muscular pains and aches, nervous indigestion, poor appetite, rheumatism, sluggish liver, sinus trouble, sour stomach, and toxic fatigue; that it was a health product; that it alone or in combination with Dr. Corley's Vitamin Tablets or with Dr. Corley's Alkaline Health Broth, or with both of those products, would constitute an efficacious treatment for swelling of the hands and other joints, soreness and stiffness of the neck and ankle, dizziness, puffed condition of veins of the back of the hands, heart trouble, and poor color in the face; that it would put the body in the condition to regain health by ridding it of its worn-out chemicals, as well as toxic, poisonous substances; that it would cleanse the body and

pave the way so that diet and a health-building program would be able to work effectively toward a speedy recovery; that it would constitute an efficacious treatment for heart trouble, ulcer, kidney disease, high blood pressure, arthritis, excess acid, digestive disturbances, and acidosis; that it would be efficacious against indigestion, acid stomach, nervousness, a tired, worn-out feeling, gastritis, colitis, hemorrhoids (piles), lumbago, neuritis, bronchitis, eczema, and overweight and underweight; that Dr. Corley's Alkalizing Health Broth would be efficacious in relieving gas, acid, bloating, and various digestive conditions, and would help clear the acid from the blood and help alkalize the system; and that Dr. Corley's Garlic Tablets would be efficacious in the treatment of inflammation of the intestines and various intestinal conditions which often cause high blood pressure.

The Alkaline Broth was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

On November 30, 1943, the defendant entered a plea of guilty and the court imposed a total fine of $450, distributed as follows: $300 on the counts involving drugs, and $150 on the counts involving foods.

1180. Misbranding of Bio-Mineral. U. S. v. 2,000 Bottles of Bio-Mineral. Default decree of destruction. (F. D. C. No. 10067. Sample Nos. 3701–F, 3731–F.)

On or about July 25, 1943, the United States attorney for the Western District of Missouri filed a libel against 2,000 bottles of Bio-Mineral at Kansas City, Mo., alleging that the article, which had been consigned on or about March 31 and May 13, 1943, had been shipped from Detroit, Mich., by the Bio-Mineral Products Co.; and charging that it was misbranded.

Analysis disclosed that the article contained, per teaspoonful, 179 milligrams of calcium, 51 milligrams of iron, and no iodine.

The article was alleged to be misbranded (1) in that the designation "Bio-Mineral," appearing on its label, was false and misleading since the mineral constituents in the article would not produce or maintain life; (2) in that the statements on its label, "Supplemental Minerals to Assist in the Prevention of Nutritional Mineral Deficiencies," and "One-half Teaspoonful (2½ c. c.) twice daily * * * will supply the minimum adult requirements of the essential minerals excepting Calcium," were false and misleading since the article contained no phosphorus, one of the mineral constituents essential in human nutrition and in the prevention of nutritional mineral deficiencies; and (3) in that the following statement on its label: "Purpose of Excess Iron in the Bio-Mineral *The Iron is present in approximately six times the minimum daily adult requirement. The purpose of this excess is to supply Iron in the lower intestines (colon). This Iron, reacting with the gaseous and other obnoxious sulfur bodies, tends to render them insoluble and hence fix these bodies to prevent reabsorption into the system. (*In stating this purpose for the excess Iron present, we are attempting to explain the results so generally attained, without claiming the existence of direct scientific evidence therefor)" was misleading since any combination of iron with sulfur compounds which may be present in the lower intestines would accomplish no useful purpose in the prevention of any disease condition.

On January 11, 1944, no claimant having appeared, judgment was entered ordering that the product be destroyed.

1181. Misbranding of Minra. U. S. v. 141 Packages and 141 Packages of Minra. Consent decree of condemnation and destruction. (F. D. C. No. 5058. Sample Nos. 55430–E, 55431–E.)

On July 8, 1941, the United States attorney for the Western District of Washington filed a libel against 141 4-ounce packages and 141 10-ounce packages of Minra at Seattle, Wash., alleging that the article had been shipped on or about January 30, 1941, from Berkeley, Calif., by the Stayner Corporation; and charging that it was misbranded.

Examination disclosed that the article contained dextrose (approximately 45 percent), citric acid (approximately 28.5 percent), sodium and potassium bicarbonates, phosphates, calcium salts (equivalent to 0.33 percent calcium oxide), iron salts (equivalent to 0.08 percent iron), small amounts of manganese and magnesium compounds, and less than 0.001 percent of copper.

The article was alleged to be misbranded (1) in that the statement on its labels, "Contains: Calcium lactate, monobasic calcium phosphate, citric acid, copper carbonate, iron lactate, magnesium citrate, manganese acetate, potassium

bicarbonate, potassium bitartrate, sodium bicarbonate and dextrose," was misleading in the absence of a statement of the material fact that the amount of calcium supplied by the preparation, when taken as directed, was substantially less than the normal requirement for calcium; (2) in that the statements on its labels, "Fatigue: The Dextrose content of this mixture contributes to fatigue relief," "The Dextrose content of this mixture contributes to the relief of fatigue," and "1 or 2 teaspoonfuls of Minra to ¾ glass of water when needed for * * * fatigue relief," were false and misleading since the article did not constitute an adequate or appropriate means of relieving fatigue; (3) in that the statement on the labels, "composed entirely of ingredients beneficial to bodily health," was misleading since the statement created the impression that the component ingredients of the article would maintain or restore bodily health, whereas the component ingredients of the article did not constitute an adequate or appropriate means of maintaining or restoring bodily health; (4) in that the statement on its labels, "Minra aids mineral metabolism when deficiencies of the minerals supplied herein are present," was false and misleading since the article, when taken in accordance with the directions, would not supply a deficiency of calcium; and (5) in that the statements appearing in the circular entitled "Facts About Minra," which accompanied the article and which represented and suggested that the article would relieve stomach distress, ward off fatigue, develop muscles, eliminate impurities from the blood, overcome excessive acidity, increase the hemoglobin, keep the body fluids more alkaline, increase resistance to minor infections such as colds, relieve headaches and acid indigestion, give a feeling of improved well-being, make an ideal "sleep promoter," help to cool the body, build strong bones and sound teeth, prevent anemia, postpone old age, prevent brittle bones and the aches and pains of old age, cause efficient use of vitamins, and relieve nausea or "morning-sickness," were false and misleading since the article would not fulfill the promises of benefits stated and implied therein.

On August 7, 1941, pursuant to an agreement between the Stayner Corporation, claimant, and the Government, an order was entered providing for a stay in the proceedings, and on July 22, 1943, an answer was filed by the claimant denying the allegations of the libel. On January 25, 1944, the claimant having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered destroyed.

1182. Misbranding of mineral oil. U. S. v. 84 Cases and 288 Cases of Mineral Oil (and 1 other seizure action against mineral oil). Decrees of condemnation. Product ordered released under bond for relabeling. (F. D. C. Nos. 10321, 11053. Sample Nos. 42549–F, 42871–F.)

On July 29 and November 26, 1943, the United States attorneys for the Eastern and Western Districts of Washington filed libels against 84 cases, each containing 12 1-quart bottles, and 288 cases, each containing 24 1-pint bottles, of mineral oil at Seattle, Wash., and 397 cases containing 24 1-pint bottles each, 12 cases containing 12 1-quart bottles each, and 14 cases containing 4 1-gallon bottles each of mineral oil at Spokane, Wash., alleging that the article had been shipped on or about May 28 and June 7, 1943, from Butler, Pa., by the Pennsylvania Refining Co.; and charging that it was misbranded.

The article was alleged to be misbranded in that the following statements: (Bottle label) "As a Substitute For Cooking Oils * * * It can be used successfully for general baking and frying purposes * * * It is also useful in the preparation of Salad Dressings as a substitute for Olive or other vegetable oils," and (display banner) "Save Your Red Points!!! Use Penn-Champ Mineral Oil for general Baking and Frying Excellent for Salad Dressing," were false and misleading since they falsely implied that mineral oil has the properties of and will function in the same way as edible vegetable cooking, baking, and frying oils, and is an oil suitable for use in salad dressing; and since the labeling failed to reveal the material fact that mineral oil may absorb certain vitamins and minerals and prevent their assimilation by the body.

The article in the Spokane lot and in a portion of the Seattle lot was alleged to be misbranded further in that the statements "Contents 1 Pint," "Contents One Quart," and "One Gallon," appearing in the labeling, were false and misleading as applied to an article that was short volume; and in that it was in package form and failed to bear a label containing an accurate statement of the quantity of the contents.

On September 28, 1943, the Penn-Champ Oil Corporation, Butler, Pa., claimant, having admitted the allegations of the libel against the Seattle lot, judgment of

condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration. On January 6, 1944, no claimant having appeared for the Spokane lot, judgment of condemnation was entered and the product was ordered delivered to hospitals and other suitable charities for medicinal purposes. Thereafter, the Roundup Grocery Co., Spokane, Wash., and the Penn-Champ Oil Corporation appeared as claimants for the Spokane lot, and on March 11, 1944, a supplemental decree was entered ordering that the product be released under bond for relabeling in a manner suitable to the Food and Drug Administration.

1183. Misbranding of Colestin Natural Mineral Water. U. S. v. 9 Cases of Colestin Natural Mineral Water. Default decree of condemnation and destruction. (F. D. C. No. 11032. Sample No. 11173–F.)

On November 1, 1943, the United States attorney for the Southern District of California filed a libel against 9 cases, each containing 24 bottles, of the above-named product at Lompoc, Calif., alleging that the article had been shipped on or about September 8, 1943, by the Colestin Mineral Water Co., from Medford, Oreg.; and charging that it was misbranded.

Examination of the article disclosed that it was mineral water containing about 0.29 percent dissolved mineral matter.

The article was alleged to be misbranded because of false and misleading statements on its label which represented and suggested that the article was effective for kidney, stomach, and rheumatic troubles, biliousness, and similar conditions.

On December 28, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1184. Misbranding of Buffalo Mineral Water. U. S. v. 37 Bottles of Buffalo Mineral Water. Default decree of condemnation and destruction. (F. D. C. No. 10930. Sample No. 46387–F.)

On October 21, 1943, the United States attorney for the Eastern District of North Carolina filed a libel against 37 5-gallon bottles of Buffalo Mineral Water at Wake Forest, N. C., alleging that the article had been shipped on or about June 21, 1943, by the Buffalo Mineral Springs Co., Inc., from Buffalo Springs, Va.; and charging that it was misbranded.

Examination disclosed that the article was a lightly mineralized water.

The article was alleged to be misbranded because of false and misleading statements appearing in the leaflet entitled "Perhaps . . . You Might Wish to Know," which represented and suggested that the article would improve or restore health; and that it was an unexcelled diuretic and would be of great benefit in the treatment of kidney disorders, diabetes, renal calculi (stone in the bladder), inflammation of the bladder, Bright's disease, constipation, stomach disorders, indigestion, gastro-intestinal disorders, jaundice, liver disorders, alcoholism, rheumatism, neuritis, arthritis, disorders of the nervous system, influenza, colds, and children's diseases.

On December 11, 1943, no claimant having appeared, judgment of condemnation was entered and it was ordered that the contents of the bottles containing the articles be destroyed and that the empty bottles, after the removal of the labels thereon, be returned to the Buffalo Mineral Springs Co., Inc.

1185. Misbranding of Vita-Pure B-Complex Vitamins. U. S. v. 16 Display Cards of Vita-Pure B-Complex Vitamins. Decree of condemnation and destruction. (F. D. C. No. 10944. Sample No. 36265–F.)

On October 20, 1943, the United States attorney for the District of Colorado filed a libel against 16 display cards to each of which were attached 24 small cartons, each containing 10 tablets, of Vita-Pure B-Complex Vitamins at Colorado Springs, Colo., alleging that the article, which had been consigned by the Roisman Products Co., had been shipped from Oklahoma City, Okla., on or about March 30, 1943; and charging that it was misbranded. The article was labeled in part: "Each Tablet Contains: Vitamin B_1 (Thiamine Chloride) 333 U. S. P. Units Vitamin B_2 (G) Riboflavin 500 micrograms."

Examination disclosed that the article contained not more than 266 U. S. P. Units of vitamin B_1 per tablet, and that it contained approximately the amount of vitamin B_2 declared on its label.

The article was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that the article would be efficacious in the prevention and correction of nervousness, loss of appetite, mental depres-

sion, skin disorders, weakness, neuritis, constipation, fatigue, faulty memory, and nutritional anemia; that it would help keep one feeling fit; and that 1 tablet per day of the article would afford the average minimum requirements of adult persons for B-complex vitamins, were false and misleading since the article would not effect the results suggested or implied, and it would not furnish the minimum adult requirements for vitamin B_2, one of the B-complex vitamins.

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in the notices of judgment on foods.

On October 30, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1186. Misbranding of Huzzah A Vitamin B_1 & B_2 Supplement. U. S. v. 42 Cases of Huzzah A Vitamin B_1 & B_2 Supplement, and 33 Cartons of Printed Material. Default decree of condemnation and destruction. (F. D. C. No. 12276. Sample No. 54833–F.)

On May 5, 1944, the United States attorney for the Eastern District of Wisconsin filed a libel against 42 cases, each containing 12 1-pint bottles, of the above-named article, and 33 cartons of printed material, containing a supply of circulars, a number of leaflets, and a number of display cards and streamers, at Milwaukee, Wis., alleging that the article and printed material had been shipped in interstate commerce on or about November 20, 1943, from Chicago, Ill., by the Huzzah Corporation of America; and charging that the article was misbranded. The printed material was entitled: (Circular) "What Is Huzzah," (leaflet) "Huzzah A Vitamin Drink Supplement," and (display card and streamer) "Feel Better Tomorrow."

Examination showed that the article was essentially a water solution of glycerin, caramel, and phosphoric acid, and that it contained vitamin B_1 and riboflavin.

The article was alleged to be misbranded in that the statements in its labeling which represented and suggested that use of the article would prevent physiological reactions due to overindulgence in alcoholic beverages; that it would prevent or correct the various conditions named, which included low resistance to alcoholic stimulants, nervousness, exhaustion, a fagged-out feeling, headaches, faulty digestion, lack of appetite, stunted growth, polyneuritis, and certain skin disorders; and that it would insure energy and strength, were false and misleading since the article would not accomplish the results stated or implied.

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in the notices of judgment on foods, No. 6200.

On June 13, 1944, no claimant having appeared, judgment of condemnation was entered and the product, together with the printed material, was ordered destroyed.

1187. Misbranding of Himrod's Asthma Powder. U. S. v. 19 Dozen Packages of Himrod's Asthma Powder. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 6536. Sample No. 74166–E.)

On December 18, 1941, the United States attorney for the Eastern District of New York filed a libel against 19 dozen packages of the above-named product at Brooklyn, N. Y., alleging that the article had been shipped from Hoboken, N. J., by the Himrod Manufacturing Co. on or about October 8 and November 14, 1941; and charging that it was misbranded. On December 9, 1942, an amended libel was filed in clarification of the charge of misbranding.

Examination disclosed that the article consisted essentially of a mixture of stramonium and potassium nitrate.

The article was alleged to be misbranded (1) in that the designation "Himrod's Asthma Powder," appearing upon the carton, the metal container, and the booklet enclosed in the package, was false and misleading since it created the impression that the article was a treatment for asthma, whereas the article was not a treatment for asthma but was merely a temporary palliative for the acute temporary manifestations of that disease; (2) in that the statement in the labeling of the article, "To relieve the paroxysms of Asthma and Asthmatic Hay Fever," was false and misleading since it represented and suggested that the article would relieve the paroxysms of asthmatic hay fever, whereas it would not relieve such paroxysms; and, since the words "Asthma" and "Hay Fever" were given much greater prominence than were the words "To relieve the paroxysms of," the impression was created that the article was a treatment for asthma and hay fever, whereas it was not; and (3) in that certain statements appearing in its labeling which created the impression that the article would accomplish more

than a temporary relief of the spasms of bronchial asthma, and that the use of the article would result in decreasing the severity and frequency of such spasms, causing their ultimate disappearance, were false and misleading since the article would not accomplish such results.

On January 31, 1944, the Himrod Manufacturing Co., claimant, having filed an answer denying the misbranding of the product, and later having withdrawn its answer and consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond to be brought into compliance with the law under the supervision of an employee designated by the Federal Security Administrator.

1188. Misbranding of Opera Tablets. U. S. v. 34 Packages of Opera Tablets. Default decree of condemnation and destruction. (F. D. C. No. 11064. Sample No. 51343–F.)

On November 4, 1943, the United States attorney for the District of Rhode Island filed a libel against 34 packages of Opera Tablets at Pawtucket, R. I., alleging that the article had been shipped on or about September 25, 1943, from Webster, Mass., by the Goodness Bros. Co.; and charging that it was misbranded.

Examination of a sample of the article disclosed that the tablets were composed of a mixture of powdered plant drugs including buchu, aloe, gamboge, capsicum, and ginger.

The article was alleged to be misbranded because of false and misleading statements in its labeling which represented and suggested that the article was effective in the treatment of eczema, skin diseases, general debility, obesity, bladder trouble, blood poisoning, yellow skin, yellow blotches, liver spots, pains in the side, blood rushing, rings around the eyes, a heavy, tired feeling, watery blood, wind on the stomach, gases, swollen sides, headaches, fits, fainting spells, dyspepsia, catarrh of the stomach, dropsy, sore joints, anemia, jaundice, biliousness, costiveness, heart-flush spells, loss of appetite, pimples, sleeplessness, worry, rheumatism, swollen joints, gall stones, heart trouble, bed wetting, kidney diseases, backache, weakness, dizziness, vertigo, painful urination, gravel in the urine, irritable temperament, fever, uric acid, blood poisoning, shortness of breath, epilepsy, urinary weakness, constipation, pallor, coated tongue, yellowing of the whites of the eyes, enlargement, hardness, and atrophy of the liver, loss of desire for exercise, diarrhea, appendicitis, and melancholia. It was alleged to be misbranded further in that it was fabricated from two or more ingredients and its label failed to bear the common or usual name of each active ingredient.

On December 4, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1189. Misbranding of Car-Bo-Ak. U. S. v. 23½ Dozen Packages of Car-Bo-Ak. Decree of condemnation. Product ordered released under bond. (F. D. C. No. 11027. Sample No. 39790–F.)

On November 3, 1943, the United States attorney for the District of Arizona filed a libel against 23½ dozen packages of Car-Bo-Ak at Phoenix, Ariz., alleging that the article, which had been consigned by the Brunswig Drug Co., Los Angeles, Calif., had been shipped on or about November 23, 1942; and charging that it was misbranded. The article was labeled in part: "CAR-BO-AK * * * A pharmaceutical compound of principles of medicinal plants. Containing Burdock, Licorice Root, Poke Root, Xanthoxylum Stillingia, Sarsaparilla. * * * Prepared for John L. Van Houten * * * Temple City, California."

Examination disclosed that the article consisted essentially of water, alcohol, and extracts of plant materials, including licorice.

The article was alleged to be misbranded because of false and misleading statements appearing in its labeling which represented and suggested that it was effective as an alterative, as a blood tonic, and as a relief for rheumatic conditions, improper elimination, and auto-intoxication; and that it was effective in the treatment of skin diseases such as scrofula, carbuncles, boils, sties, and acne pimples.

On December 23, 1943, John L. Van Houten having appeared as claimant, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

1190. Misbranding of Citra Nesia. U. S. v. 800 Bottles of Citra Nesia. Default decree of condemnation and destruction. (F. D. C. No. 10821. Sample No. 39468–F.)

On or about November 6, 1943, the United States attorney for the District of Arizona filed a libel against 800 bottles of Citra Nesia at Phoenix, Ariz., alleging

that the article, which had been consigned by the Monarch Products Co., Los Angeles, Calif., had been shipped from on or about June 5 to July 6, 1943; and charging that it was misbranded.

Examination disclosed that the article consisted of an effervescent solution containing sodium phosphate, sugar, and a citrate, and that it did not contain citrate of magnesia.

The article was alleged to be misbranded (1) in that it was an imitation of another drug, solution of magnesium citrate (citrate of magnesia); (2) in that the statement "Contents 12 Fluid Ounces" appearing on its label, was false and misleading as applied to the article, which was short volume; and (3) in that the label did not bear an accurate statement of the quantity of contents.

On March 28, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1191. Misbranding of Pine Bros. Menthol Glycerine Tablets and Licorice Glycerine Tablets. U. S. v. 35½ Dozen Packages of Menthol Glycerine Tablets and 35½ Dozen Packages of Licorice Glycerine Tablets. Default decree of condemnation. Portion of product ordered delivered to the Food and Drug Administration; remainder ordered delivered to a charitable institution. (F. D. C. No. 11017. Sample No. 57343–F.)

On October 28, 1943, the United States attorney for the Southern District of New York filed a libel against the above-described products at New York, N. Y., alleging that the articles had been shipped from Philadelphia, Pa., by Pine Bros., on or about October 2, 1943; and charging that they were misbranded. The articles were labeled in part: "Pine Bros. Glycerine Tablets Menthol [or "Licorice"]."

They were alleged to be misbranded in that the statement "Net Weight 1⅓ Oz.," borne on the label of the menthol-flavored tablets, and the statement "Net Weight 1.25 Oz." borne on the label of the licorice-flavored tablets, were false and misleading as applied to articles that were short weight; and in that they were in package form and their labels failed to bear an accurate statement of the quantity of the contents.

On November 24, 1943, no claimant having appeared, judgment of condemnation was entered and it was ordered that a portion of the product be delivered to the Food and Drug Administration, and that the remainder be delivered to a charitable institution.

1192. Misbranding of pentothal sodium with distilled water. U. S. v. 4,536 Packages of Pentothal Sodium with Distilled Water. Decree of condemnation. Product ordered released under bond. (F. D. C. No. 11265. Sample No. 29631–F.)

On December 18, 1943, the United States attorney for the Northern District of California filed a libel against 4,536 packages of the above-named product at San Francisco, Calif., alleging that the article had been shipped from North Chicago, Ill., by the Abbott Laboratories, on or about November 15 and 16, 1943; and charging that it was misbranded.

The article was alleged to be misbranded in that the statements appearing on its label, "Chemically Pure Water," "Dissolve the contents of the ampoule of Pentothal Sodium in the 50 cc. of sterile chemically pure water * * * For intravenous injection," and "This water has been purified by a special process," were false and misleading since they represented and suggested that the article was suitable for the preparation of a solution of pentothal sodium for intravenous administration, whereas it was not so suitable because the distilled water contained undissolved particles.

On December 29, 1943, Abbott Laboratories having appeared as claimant, judgment of condemnation was entered and the product was ordered released under bond to be brought into compliance with the law, under the supervision of the Food and Drug Administration.

1193. Misbranding of Scalp Lotion A and Scalp Lotion B. U. S. v. 49 Packages of Scalp Lotion A and 23 Packages of Scalp Lotion B. Default decree of condemnation and destruction. (F. D. C. No. 10691. Sample Nos. 56556–F, 56557–F.)

On or about September 9, 1943, the United States attorney for the Southern District of New York filed a libel against 22 8-ounce packages, 25 16-ounce packages, and 2 1-gallon packages of Scalp Lotion A, and 10 8-ounce packages, 12 16-ounce packages, and 1 1-gallon package of Scalp Lotion B at New York, N. Y., alleging that the articles had been shipped on or about May 28 and July

30, 1943, from Boston, Mass., by T. Noonan and Sons Co.; and charging that they were misbranded.

Examination disclosed that the Scalp Lotion A consisted essentially of water, alcohol (81.2 percent), beta naphthol, quinine, resorcinol, and a saponifiable oil such as castor oil; and that the Scalp Lotion B consisted essentially of water, alcohol (49 percent) beta naphthol, resorcinol, and perfume oils.

The articles were alleged to be misbranded in that the statements in the labeling of the Scalp Lotion A, "for the treatment of * * * Falling Hair and Alopecia Areata (Bald Spots)," and in the labeling of Scalp Lotion B, "for the treatment of Oily Hair, Oily Dandruff and Psoriasis," were false and misleading since the articles would not be effective in the treatment of the conditions named. They were alleged to be misbranded further in that their labels failed to bear the common or usual names of the active ingredients and the statement of the quantity or proportion of alcohol present.

On October 6, 1943, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

1194. Misbranding of tooth powder. U. S. v. 182 Packages and 61 Packages of Tooth Powder. Default decree of condemnation and destruction. (F. D. C. No. 10304. Sample No. 42460–F.)

On August 4, 1943, the United States attorney for the Western District of Washington filed a libel against 182 ¾-ounce packages and 61 3-ounce packages of tooth powder at Seattle, Wash., alleging that the article had been shipped on or about October 9, 1942, and March 17, 1943, from Long Beach, Calif., by the Frenco Laboratories; and charging that it was misbranded. The article was labeled in part: "Frenco's Papaya Tooth Powder."

Examination of samples disclosed that the article consisted essentially of calcium carbonate and inactive papain.

The article was alleged to be misbranded in that the statement appearing upon its label, "The danger of Pyorrhea may be greatly diminished by packing the teeth overnight with a paste made from the powder," was false and misleading since the article would not be effective in the prevention of pyorrhea.

On April 28, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1195. Misbranding of Rainier Natural Soap. U. S. v. 327 Packages of Rainier Natural Soap. Default decree of condemnation. Product ordered delivered for the use of a government institution. (F. D. C. No. 10750. Sample No. 38536–F.)

On September 16, 1943, the United States attorney for the Northern District of Illinois filed a libel against 327 packages of the above-named product at Chicago, Ill., alleging that the article had been shipped from South Boston, Mass., by the Rainier Natural Soap Co., on or about June 30, 1943; and charging that it was misbranded.

Examination disclosed that the article consisted essentially of approximately 32 percent soap and 68 percent pumice or a similar mineral.

The article was alleged to be misbranded because of false and misleading statements appearing in its labeling which represented and suggested that it was a naturally occurring soap and would be effective in the prevention and treatment of eczema, rashes, poison ivy, chafing, and other externally caused skin irritations, itching and burning skin conditions, blackheads, pimples, and other disfiguring blotches.

On January 13, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered delivered for the use of a government institution.

DRUGS FOR VETERINARY USES

1196. Misbranding of Dr. Daniels' Wind Colic Drops and Veterinary C. C. & F. Drops. U. S. v. 69 Packages of Dr. Daniels' Wind Colic Drops and 9 Packages of Dr. A. C. Daniels' Veterinary C. C. & F. Drops. Default decree of condemnation and destruction. (F. D. C. No. 10786. Sample Nos. 20582–F, 20583–F.)

On September 17, 1943, the United States attorney for the District of Maine filed a libel against 69 packages of the Wind Colic Drops and 9 packages of the C. C. & F. Drops at Portland, Maine, alleging that the articles had been shipped on or about August 13, 1943, by Dr. A. C. Daniels, Inc., from Boston, Mass.; and charging that they were misbranded.

Examination of the Wind Colic Drops disclosed that each retail package contained 2 1-ounce bottles, designated as No. 1 and No. 2. Analyses showed that the contents of bottle No. 1 consisted essentially of alcohol and water with extract of nux vomica; and that of bottle No. 2 consisted essentially of alcohol and water with extract of colocynth. The article was alleged to be misbranded (1) because of false and misleading statements on the label which represented and suggested that it was an adequate treatment for flatulent colic, also known as wind colic and bloat colic with its anomalies, (2) in that the statement on the label, "Use Dr. A. C. Daniels C. C. & F. Drops for relief of Coughs Colds and Fevers for Horses," was a false and misleading claim in respect to another drug; (3) in that neither bottle bore a label containing the name and place of business of the manufacturer, packer, or distributor, or an accurate statement of the quantity of contents in terms of weight, measure, or numerical count; and (4) in that neither bottle bore a label declaring the common or usual name of each active ingredient.

Analysis of the C. C. & F. Drops disclosed that the article consisted essentially of alcohol and water with extracts of alkaloid-bearing plant drugs such as belladonna and aconite. It was alleged to be misbranded in that the statement in its labeling which represented and suggested that it was an adequate treatment of febrile conditions associated with respiratory disturbances of horses was false and misleading since it was not an adequate treatment for such conditions.

On October 22, 1943, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

1197. Misbranding of Southard's Red Comb. U. S. v. 261 Bottles of Southard's Red Comb. Default decree of destruction. (F. D. C. No. 9920. Sample No. 3350–F.)

On or about May 20, 1943, the United States attorney for the Western District of Missouri filed a libel against 261 8-ounce bottles of the above-named product at Kansas City, Mo., alleging that the article, which had been consigned on or about April 3, 1943, had been shipped from Kansas City, Kans., by the Curts-Folse Laboratories; and charging that it was misbranded.

Analysis disclosed that the article consisted essentially of water with small amounts of salt, potassium permanganate, sodium sulfate, and potassium chlorate.

The article was alleged to be misbranded in that the picture on the label of a rooster with a red comb, and the name "Red Comb," were misleading since they represented and suggested that the article would maintain a red comb on roosters or chickens, indicating a healthy condition of the bird, whereas the article would not maintain a red comb on roosters or chickens; and in that the statement on the label, "Poultry Remedy For Many Common Diseases of Poultry," was false and misleading since it represented and suggested that, when used as directed, the article was effective as a remedy for many known common diseases of poultry, whereas it was not effective as a remedy for any known common diseases of poultry.

On January 6, 1944, no claimant having appeared, judgment was entered ordering that the product be destroyed.

1198. Misbranding of Korum. U. S. v. 16 Bottles, 34 Bottles, and 8 Bottles of Korum. Default decree of condemnation and destruction. (F. D. C. No 10119. Sample Nos. 6955–F to 6957–F, incl.)

On July 6, 1943, the United States attorney for the Southern District of Illinois filed a libel against the above quantities of Korum at Edwardsville, Ill. On November 17, 1943, the libel was amended to cover additional goods, making a total of 15 1-gallon, 50 32-ounce, 105 16-ounce, and 16 8-ounce bottles of Korum. It was alleged in the libel that the article had been shipped on or about May 29, 1943, from Kansas City, Mo., by the I. D. Russell Co., and that it was misbranded.

Analysis showed that the article contained, per 100 cc., 5.61 grams of sodium chloride, 4.03 grams of potassium dichromate, 3.64 grams of Epsom salt, 155 grams of sodium chlorate, 1.46 grams of potassium nitrate, and water.

The article was alleged to be misbranded because of false and misleading statements in the accompanying labeling, which consisted of a booklet entitled "Russel Poultry Medicines and Biologics," and leaflets entitled "Questions Often Asked By Poultry Raisers and Answers," and "Turkey Pointers," and which represented and implied that the article, when used as directed, would be effective in the prevention or treatment of any cause of diarrhea; that it would aid in dissolving mucus; that it would be effective as a laxative in keeping

the intestinal tract clean or in keeping the flock in better health; that it would aid greatly in the prevention and treatment of blackhead and trichomoniasis in poultry; that it would prevent birds from becoming sick; that it would be effective in keeping birds in better condition, and thereby increase poultry profits; that it would be effective in the prevention or treatment of any form of coccidiosis or mycosis; and that it would aid in the elimination from poultry of any disease condition.

On November 17, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1199. Misbranding of Wayne Flushing Mash. U. S. v. 160 Bags of Wayne Flushing Mash. Default decree of condemnation. Product ordered delivered to a Federal institution, for use as animal feed. (F. D. C. No. 11755. Sample No. 59532–F.)

On February 11, 1944, the United States attorney for the Eastern District of Michigan filed a libel against 160 bags, each containing 25 pounds, of the above-named product at Centerline, Mich., alleging that the article had been shipped by Allied Mills, Inc., Fort Wayne, Ind., between the approximate dates of October 28 and November 27, 1943; and charging that it was misbranded.

Examination disclosed that the article consisted essentially of carbohydrates, protein, fats, bran, small amounts of the carbonates, sulfates, chlorides, iodides and phosphates of calcium, iron, sodium, and manganese.

The article was alleged to be misbranded in that the statements appearing in an accompanying circular which represented and suggested that the article would be effective in the prevention or treatment of coccidiosis and would be an aid in preventing disease in chickens were false and misleading since the article would not be effective in the prevention or treatment of coccidiosis or any other disease condition of chickens.

On March 14, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to a Federal institution, for use as animal feed.

1200. Misbranding of flushing mash. U. S. v. 40 Bags of Flushing Mash. Decree of condemnation. Product ordered released under bond. (F. D. C. No. 10988. Sample No. 50437–F.)

On or about October 22, 1943, the United States attorney for the District of Delaware filed a libel against 40 100-pound bags of flushing mash at Roxanna, Del., alleging that the article had been shipped from Cincinnati, Ohio, by Cooperative Mills, Inc., on or about August 13, 1943; and charging that it was misbranded. The article was labeled in part: "Cooperative Mills Quality * * * Flushing Mash."

Analysis disclosed that the article was essentially a feed mixture containing 17 percent crude protein, 13 percent crude fat, and 6 percent crude fiber.

The article was alleged to be misbranded in that the statements on its label which represented and suggested that, when fed according to directions, it would be of value in the treatment or prevention of cecal or acute coccidiosis, were false and misleading since the article would not be of any value in the treatment or prevention of cecal or acute coccidiosis.

On January 22, 1944, the Southern States Cooperative having appeared as claimant through its subsidiary, the Cooperative Mills, Inc., judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

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PRODUCTS

SHIPPERS AND MANUFACTURERS

[1](1157) Seizure contested. Contains court opinions.

U. S. GOVERNMENT PRINTING OFFICE: 1945

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

1201–1250

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

WATSON B. MILLER, *Acting Administrator, Federal Security Agency.*

WASHINGTON, D. C., *April 30, 1945.*

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DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

1201. Adulteration and misbranding of Nelson's Antacid Powder and misbranding of B-M Cold Caps. U. S. v. The Cleveland Druggists Specialties Co. (Great Lakes Laboratories), and Bernard A. Saltzman. Pleas of guilty. Fine of $450 plus costs against each defendant. Payment of fine and costs of corporate defendant suspended. (F. D. C. No. 10541. Sample Nos. 6597–F to 6599–F, incl.)

On September 16, 1943, the United States attorney for the Northern District of Ohio filed an information against the Cleveland Druggists Specialties Co., a corporation trading under the name of Great Lakes Laboratories, Cleveland, Ohio, and against Bernard A. Saltzman, president of the corporation, alleging shipment from the State of Ohio into the State of Missouri of a quantity of B-M Cold Caps, on or about January 2, 1943, and a quantity of Nelson's Antacid Powder, on or about May 25, 1942.

Analysis of the Cold Caps disclosed that the article was in the form of capsules which contained acetanilid, aspirin, caffeine, extracts of plant drugs, including a laxative drug and an alkaloid-bearing drug, and capsicum.

The article was alleged to be misbranded (1) in that each capsule contained 1.72 grains of acetanilid and would be dangerous to health when used in the dosage

*For omission of, or unsatisfactory, ingredients statements, see Nos. 1201, 1202, 1204, 1234, 1235, 1239; failure to bear adequate statements of quantity of contents, Nos. 1229, 1238, 1240, 1248; cosmetics, subject to the drug provisions of the Act, Nos. 1239, 1240.

or with the frequency prescribed, recommended, or suggested in the directions borne on the label, "One capsule every 2 or 3 hours with a glassful or more of water"; (2) in that the statement "For Temporary Relief of Minor Colds, Flu," borne on the label, was false and misleading since the article would not be efficacious as a temporary relief of minor colds and flu; (3) in that the article was fabricated from two or more ingredients and contained the alkaloids of atropine, hyoscine, and hyoscyamine, as constituents of belladonna, and its label did not bear the name and quantity or proportion of the said alkaloids or, in lieu thereof, the quantity or proportion of total alkaloids contained in the article as constituents of belladonna; (4) in that its labeling failed to bear adequate directions for use since the directions on the label provided for the administration of excessive amounts of acetanilid; and (5) in that its labeling failed to bear adequate warnings against use or against unsafe dosage or duration of administration, since its labeling did not bear warning that it might cause serious blood disturbances, anemia, collapse, or dependence on the drug; that it should not be used frequently or continuously; that it should be used cautiously if dryness of the throat occurred; that its use should be discontinued if rapid pulse or blurring of vision occurred; and that continued use of the article, which was a laxative, might result in the dependence of the user upon laxatives to move the bowels.

Analysis of Nelson's Antacid Powder disclosed that the article consisted essentially of compounds of sodium, calcium, magnesium, and carbonate, and that it contained no bismuth salts.

The article was alleged to be adulterated in that its strength differed from that which it purported to possess since it purported to contain bismuth salts, whereas it contained no bismuth salts. It was alleged to be misbranded in that the statement "Bismuth Salts in the form of Carbonates Subnitrates," borne on the label, was false and misleading. It was alleged to be misbranded further because of false and misleading statements in its labeling which represented and suggested that the article would be efficacious in the treatment of gastric ulcers, gastralgia, gastritis, and acidosis; that it would form a soothing, protecting coating over the highly inflamed mucous membranes of the stomach; that it was mildly astringent and sedative; that it would convert all protein foods such as meats and albumens into soluble and readily absorbed peptones; that it would convert all starchy foods into soluble dextrins and sugars; that it would be efficacious in treatment of functional stomach disorders and indigestion; that it was a strictly scientific preparation which offered a rational and effective method of reestablishing the normal alkalinity of the body fluids without danger of systemic disturbance; that it would instantly neutralize all stomach acids; and that it would be efficacious as an instant relief from acidity and gas pressure. It was alleged to be further misbranded in that its label failed to bear an accurate statement of the quantity of contents.

On October 25, 1943, pleas of guilty having been entered, the court imposed a fine of $150 on each of 3 counts, a total fine of $450 plus costs, against each defendant. Payment of the fine and costs against the corporate defendant was suspended.

1202. Misbranding of Grover Graham Remedy. U. S. v. 22 Bottles and 22 Bottles of Grover Graham Remedy (and 4 other seizure actions against the same product). Default decrees of condemnation and destruction. (F. D. C. Nos. 11750, 11816, 11867, 11868, 11977. Sample Nos. 47774–F, 50750–F, 51636–F, 65932–F, 76308–F.)

Between February 5 and March 10, 1944, the United States attorneys for the Eastern District of Missouri, the District of New Jersey, the District of Massachusetts, and the Middle District of Pennsylvania filed libels against the following quantities of the above-named product, contained in 6-ounce and 12-ounce size bottles: 44 bottles at St. Louis, Mo., 65 bottles at Newark, N. J., 60 bottles at Boston, Mass., 82 bottles at Hackensack, N. J., and 18 bottles at Northumberland, Pa., alleging that the article had been shipped on or about December 6 and 21, 1943, and January 24, 1944, from Newburgh, N. Y., by the Grover Graham Co., Inc.; and charging that it was misbranded.

Examination of samples disclosed that the article consisted essentially of magnesia, sodium bicarbonate, sodium bromide, equivalent to 8¼ grains or 8.4 grains per tablespoonful, alcohol, chloroform, oil of peppermint, and coloring matter.

The article was alleged to be misbranded in that the statements on its label which represented and suggested that it would be efficacious in the treatment

of indigestion, dyspepsia, symptoms of indigestion, and other ailments due to imperfect or retarded functioning of the digestive organs, and that the article could be taken with perfect safety, were false and misleading since the article was not an adequate treatment for the conditions, ailments, and symptoms mentioned; and it could not be taken with perfect safety inasmuch as it contained a material proportion of sodium bromide.

The article was alleged to be further misbranded (1) in that its labels did not bear adequate directions for use since the directions appearing thereon, "Directions * * * Take a large tablespoonful after meals three times a day or whenever symptoms of indigestion occur. * * * Dose should be half a wineglassful followed by another dose in a half hour if necessary. The Remedy may be taken with perfect safety as often as necessary," provided for an excessive amount of sodium bromide and placed no limitation on the number of doses to be taken daily; (2) in that its labeling failed to bear any warnings that frequent or continued use of the article might lead to mental derangement, skin eruptions, or other serious effects, and that the article should not be taken by those suffering from kidney disease; and (3) in that it was dangerous to health when used in the dosage, or with the frequency prescribed, recommended, or suggested in the labeling, "Dose should be half a wineglassful followed by another dose in a half hour if necessary. The remedy may be taken with perfect safety as often as necessary."

The article, with the exception of that in the Newark lot, was alleged to be further misbranded in that the statement of the quantity or proportion of sodium bromide contained in the article did not appear on its label in such terms as to render it likely to be understood by the ordinary individual, since the statement on the label read "Sodium Bromide U. S. P. 3½%," whereas, in order to be understood by the ordinary individual, the sodium bromide contained in the article should have been declared in terms of grains per tablespoonful.

Between March 7 and September 6, 1944, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

PRODUCTS REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

1203. Misbranding of Dimels. U. S. v. 68 Bottles and 1 Bottle of Capsules Dimels. Decree of condemnation and destruction. (F. D. C. No. 9914. Sample No. 3345–F.)

On or about May 12, 1943, the United States attorney for the Western District of Missouri filed a libel against 68 100-capsule bottles and 1 500-capsule bottle of the above-named product at Kansas City, Mo., alleging that the article had been shipped on or about March 11, 1943, from McKeesport, Pa., by Jones-Hague, Inc.; and charging that it was misbranded.

Examination disclosed that each capsule contained approximately 5 grains of a mixture of dried, powdered animal material and kaolin (China clay). The animal material was apparently of a glandular nature such as pancreas. It contained a small proportion of insulin and a starch-splitting enzyme equivalent to ½ percent pancreatin.

The article was alleged to be misbranded (1) in that it was a drug composed partly of insulin that was not from a batch for which a certificate or release had been issued pursuant to the law; (2) in that the statement on the label, "Each capsule contains Hormone Complexes as found in Isles Langerhans * * * Dosage—One capsule three times daily," was misleading in the absence of a statement of the material fact that, when consumed in accordance with the directions on the label, the article would not produce the well-known effects of the hormones found in the islands of Langerhans; and (3) in that the statements on the label, "To be taken only upon advice of physician. Its use otherwise may be dangerous. To be used only in uncomplicated and incipient Diabetes," were false and misleading since the article, if taken otherwise than upon advice of a physician, would not be dangerous, and it would be useless in the treatment of diabetes.

On January 11, 1944, Jones-Hague, Inc., having previously filed an answer denying the allegations of the libel and a brief in support of such answer, but having failed to make any further appearance in the proceedings, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

1204. Misbranding of Helping Hand Laxative Tonic. U. S. v. 310 Bottles of Helping Hand Laxative Tonic. Default decree of condemnation and destruction. (F. D. C. No. 11102. Sample No. 48710–F.)

On or about November 13, 1943, the United States attorney for the Western District of Kentucky filed a libel against 310 bottles of the above-named product at Bowling Green, Ky., alleging that the article had been shipped on or about June 24, 1943, from Nashville, Tenn., by the National Medicine Co.; and charging that it was misbranded.

Analysis disclosed that the article consisted essentially of Epsom salt, 108 grains per fluid ounce; iron and ammonium citrate, 1.1 grains per fluid ounce; and extracts of plant drugs, including laxative and bitter drugs, a sugar, a benzoate, alcohol, and water. The product contained no glycerin.

The article was alleged to be misbranded (1) in that the word "Tonic" in the name of the product, and the statements, "Acts as * * * tonic," "Recommended * * * to tone up the system," and "As * * * tonic," were false and misleading since the article contained no significant amount of any tonic ingredient and would not act as a tonic; (2) in that the labeling statements, "Active Ingredients * * * Iron and Ammonium Citrate * * * Glycerine," were misleading since the article contained no glycerin and the proportion of iron and ammonium citrate present was essentially inconsequential when the product was consumed in accordance with the directions on the label; and (3) in that its labeling failed to bear adequate directions for use, since the article was a laxative and the directions appearing in its labeling provided for continuous administration, whereas a laxative should not be used continuously.

On February 18, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1205. Misbranding of Doryl. U. S. v. 45 Ampuls of Doryl (and 4 other seizure actions against Doryl). Default decrees of condemnation and destruction. (F. D. C. Nos. 11504 to 11506, incl., 11512, 11546, 11553, 11568. Sample Nos. 29923–F, 29925–F, 29926–F, 30385–F, 30388–F, 30389–F, 35242–F, 48154–F, 57048–F, 57049–F, 58612–F, 58613–F.)

Between December 28, 1943, and January 14, 1944, the United States attorneys for the Northern District of California, the District of Columbia, the Eastern District of New York, the Western District of Kentucky, and the Southern District of Florida filed libels against the following quantities of Doryl: 26 ampuls at San Francisco, Calif., 9 ampuls at Oakland, Calif., 10 ampuls at San Mateo, Calif., 6 ampuls at Washington, D. C., 10 ampuls at Brooklyn, N. Y., 7 ampuls at Hopkinsville, Ky., and 10 ampuls at Miami, Fla., alleging, in the case of the District of Columbia lot, that the product was in interstate commerce, and, in the case of the other lots, that they had been shipped between the approximate dates of February 4, 1942, and May 6, 1943, from St. Louis, Mo., and Rahway, N. J., by Merck & Co., Inc.; and charging that all lots were misbranded. The article was labeled in part: "0.15 Gm. Ampul * * * Doryl (Carbamylcholine Chloride Merck)."

Examination of samples disclosed that the article had the composition stated upon its label.

The article was alleged to be misbranded (1) in that the statement on its label, "Do not use intravenously," was misleading since it suggested and implied that other methods of injections were safe, and its label failed to reveal the fact material in the light of such statement that the contents of the ampul were lethal when injected by any method; (2) in that its labeling bore no warning against injection of the article other than intravenously; (3) in that its container was so made, formed, and filled as to be misleading since it was in a form in which drugs intended for injection are sometimes packaged; and (4) in that its labeling failed to bear adequate directions for use since the statements in its labeling, "Do not use intravenously," and "for Ophthalmologic Use," were inadequate since they failed to reveal that the article was intended not to be used for injection but only in solution for ophthalmologic purposes.

Between April 17 and October 25, 1944, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

*See also Nos. 1201, 1202.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

1206. Adulteration of senna and senna siftings. U. S. v. 14 Bales and 26 Bales of Senna and 25 Bales of Senna Siftings. Default decree of condemnation and destruction. (F. D. C. No. 11470. Sample Nos. 46665–F to 46667–F, incl., 46671–F to 46673–F, incl.)

Senna is a vegetable drug the name of which is recognized in the United States Pharmacopoeia, and senna siftings is a term applied to small pieces of senna leaves which have been broken in the process of gathering, packing, etc.

On December 21, 1943, the United States attorney for the Eastern District of Michigan filed a libel against 40 bales of senna and 25 bales of senna siftings at Detroit, Mich., alleging that the articles had been shipped on or about June 4, 1943, by the Sterling Products Division (Sterling Drug, Inc.), Wheeling, W. Va.; and charging that they were adulterated.

The articles were alleged to be adulterated (1) in that they consisted in whole or in part of filthy substances by reason of the presence of webbing, adult insects, insect larvae, insect fragments and capsules, and insect excreta; (2) in that they had been held under insanitary conditions whereby they may have become contaminated with filth; and (3) in that they purported to be and were represented as senna, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but their quality and purity fell below the standard set forth in that compendium.

On March 11, 1944, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

1207. Adulteration and misbranding of dicalcium phosphate with vitamins B-C-D. U. S. v. Walker Vitamin Products, Inc. Plea of guilty. Fine, $100. (F. D. C. No. 7321. Sample No. 70638–E.)

On March 30, 1944, the United States attorney for the Southern District of New York filed an information against the Walker Vitamin Products, Inc., Mt. Vernon, N. Y., alleging shipment of a quantity of the above-named product on or about January 12, 1942, from the State of New York into the State of Georgia.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess.

The article was alleged to be misbranded in that the statement on its label, "In Each Capsule * * * Vitamin D (Natural) 330 I. U.," was false and misleading since each capsule of the article contained not more than 165 International Units of vitamin D.

The article was also alleged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

On April 12, 1944, a plea of guilty having been entered on behalf of the defendant, the court imposed a fine of $100.

1208. Adulteration and misbranding of Vitasol. U. S. v. Vitasol Corporation. Plea of guilty. Fine of $500 on count 1. Sentence suspended on count 2, and defendant placed on probation for 2 years. (F. D. C. No. 7731. Sample No. 69503–E.)

On April 3, 1943, the United States attorney for the Eastern District of New York filed an information against the Vitasol Corporation, Brooklyn, N. Y., alleging shipment on or about July 15, 1941, from the State of New York into the State of Connecticut of a quantity of Vitasol which was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it was represented to possess, since it was represented to contain approximately 1,000 U. S. P. units of vitamin A per ounce, or 40,000 per 2½ pounds; 150 International Units of vitamin B_1 per ounce, or 6,000 per 2½ pounds; and 0.0067 gram of iron and 0.170 gram of phosphorus per ounce, whereas it contained not more than 750 U. S. P. units of vitamin A per ounce, or 30,000 units per 2½ pounds; 100 International Units of vitamin B_1 per ounce, or 4,000 International Units per 2½ pounds; and not more than 0.0015 gram of iron and 0.1206 gram of phosphorus per ounce.

The article was alleged to be misbranded because of the following false and misleading statements on its label, "Approximate Vitamin Contents in 2½ Lbs. of Vitasol 40,000 U. S. P. Units Vitamin A 6,000 International Units Vitamin B_1,"

*See also Nos. 1201, 1206.

and "Approximate composition of one ounce of Vitasol 1,000 U. S. P. Units Vitamin A 150 International Units Vitamin B_1 * * * Grams Per Ounce * * * Iron—0.0067 Phosphorus—0.170."

It was alleged to be misbranded further in that the statements, "Vitasol * * * Health Builder * * * Dedicated to the Betterment of Health * * * Vitamin A is vital to eyesight. Vitamins B_1, B_2 (G) stimulates the appetite, aids digestion. Vitamin C Favors good bone and tooth formation, prevents scurvy. The 'Sunshine Vitamin D' is important to general health, utilizes calcium and phosphorus in building strong teeth and bones. Organic Iron helps increase red corpuscle growth. Yeast as an aid to good blood and body functions. Dextrose for restoring energy. Soy Bean rich in protein (strength food). * * * Vitasol * * * health builder * * * quick revitalizing food for all active adults. Vitamins Vigor Vitality," borne on the jar label, were misleading since they suggested that the article would prevent scurvy; that impaired health, poor eyesight, poor appetite and digestion, poor teeth and bones, general ill health, inadequate red corpuscle growth, poor functioning of the blood and body, low energy, weakness, poor health, and lack of vitality and vigor are frequently caused by lack of the vitamins and other substances named; and that the reader might reasonably expect that the article would be efficacious in the prevention of scurvy and in conditions of impaired health as described above, whereas the article would not prevent scurvy, the conditions of impaired health as described are not frequently caused by lack of the vitamins or other substances named in the labeling, but usually result from other causes, and the reader might not reasonably expect the article to be efficacious to prevent scurvy or better such conditions of impaired health.

The article was alleged to be misbranded further in that the statements, "Vitasol * * * prepared to provide a wide variety of protecting food elements (not available in the ordinary diet) essential to abundant vitality and health," borne on the jar label, were false and misleading since the article would not provide a wide variety of protecting food elements that are not available in the ordinary diet and are essential to abundant vitality and health.

The article was also alleged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in the notices of judgment on foods.

On April 22, 1943, the defendant having entered a plea of guilty to the 2 counts of the information, the court imposed a fine of $500 on count 1. Sentence was suspended on count 2, and the defendant was placed on probation for 2 years.

1209. Adulteration and misbranding of Estrovin in Oil and sodium morrhuate. U. S. v. The Adson-Intrasol Laboratories, Inc. Plea of guilty. Fine, $500 and 3 years' probation. (F. D. C. No. 7721. Sample Nos. 7697–E, 7698–E, 95341–E.)

On August 4, 1943, the United States attorney for the Southern District of New York filed an information against the Adson-Intrasol Laboratories, Inc., New York, N. Y., alleging that on or about January 28 and March 11, 1942, the defendant introduced and caused to be introduced into interstate commerce at New York, N. Y., for delivery to Los Angeles and San Francisco, Calif., quantities of Estrovin in Oil and sodium morrhuate.

The Estrovin in Oil was alleged to be adulterated in that it purported and was represented to possess, in each cubic centimeter, a biological activity equivalent to the activity of 5,000 International Units of estrogenic ovarian follicular hormones, whereas it possessed a biological activity of not more than 1,100 International Units of estrogenic ovarian follicular hormones in each cubic centimeter. It was alleged to be misbranded in that the statements in its labeling, "Estrovin In Oil * * * 1 c. c. contains therapeutic activity of 5,000 i. u. of estrogenic ovarian follicular hormones," and "Estrovin In Oil 1 c. c. 5,000 I. U.," were false and misleading.

The sodium morrhuate was alleged to be adulterated in that it purported and was represented to contain 5 percent of sodium morrhuate, whereas it contained not more than 1.1 percent of sodium morrhuate. It was alleged to be misbranded in that the statements appearing in its labeling, "Sodium Morrhuate * * * 5%," and "Sodium Morrhuate 'Intrasol' is a sterile colloidal solution containing Sodium Morrhuate * * * 5%," were false and misleading.

On August 23, 1943, the defendant entered a plea of guilty, and on August 30, 1943, the court imposed a fine of $250 to cover counts 1 and 2, and $250 to cover counts 3 and 4, a total fine of $500, and placed the defendant on probation for 3 years.

1210. Adulteration and misbranding of solution of citrate of magnesia. U. S. v. Mordecai Seidman (M. Seidman). Plea of guilty. Fine, $70 and costs. (F. D. C. No. 11390. Sample Nos. 64840–E, 21020–F, 34213–F, 37688–F.)

On April 14, 1944, the United States attorney for the Western District of Pennsylvania filed an information against Mordecai Seidman, an individual trading as M. Seidman, Pittsburgh, Pa., alleging shipment between the approximate dates of November 25, 1941, and June 22, 1943, from the State of Pennsylvania into the States of Ohio and Michigan of quantities of the above-named product. The article was labeled in part: (Bottles) "Effervescing Solution of Citrate of Magnesia. * * * Distributed by Superior Distributing Co. Pittsburgh, Pa."

Examination disclosed that the article contained approximately one-half as much syrup and, in the case of certain portions, two-thirds as much magnesium citrate, as provided by the United States Pharmacopoeia; and that various portions also contained sulfate in excess of the amount permitted by the Pharmacopoeia, and were not packaged in the manner prescribed therein.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from and its quality fell below the standard set forth therein, and its difference in strength and quality from the standard was not stated plainly, or at all, on its labels.

Various portions of the article were alleged to be misbranded (1) in that the statement on its label, "Solution of Citrate of Magnesia Made of pure citric acid and carbonate of magnesia according to the U. S. Pharmacopoeia * * * U. S. P.," was false and misleading; (2) in that it was not packaged as prescribed in the Pharmacopoeia, since that compendium provides: "Dispense Solution of Magnesium Citrate in bottles containing not less than 340 cc. and not more than 360 cc., or in bottles containing not less than 195 cc. and not more than 205 cc.," whereas the article was contained in bottles containing less than 340 cc. and more than 205 cc.; (3) in that the statement "11 Ozs.," borne on the bottle labels, was false and misleading since a number of the bottles contained less than 11 ounces of the article; and (4) in that a number of the bottles failed to bear a label containing an accurate statement of the quantity of the contents.

On May 5, 1944, the defendant having entered a plea of guilty, the court imposed a fine of $10 on each of 7 counts, a total fine of $70 and costs.

1211. Adulteration and misbranding of zinc oxide ointment, ammoniated mercury ointment, and carbolic ointment. U. S. v. The Trade Laboratories, Inc. Plea of guilty. Fine, $200. (F. D. C. No. 11364. Sample Nos. 38279–F, 38602–F, 45450–F.)

On March 23, 1944, the United States attorney for the District of New Jersey filed an information against the Trade Laboratories, Inc., Newark, N. J., alleging shipment of quantities of the above-named products on or about February 13, April 7, and May 17, 1943, from the State of New Jersey into the States of Illinois and New York.

The zinc oxide ointment was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from the standard set forth therein since the compendium provides that zinc oxide ointment shall contain not less than 18.5 percent and not more than 21.5 percent of zinc oxide, whereas portions of the article contained zinc oxide in amounts varying from 12.84 percent to 17.98 percent, and a portion of the article contained not less than 22.65 percent of zinc oxide, and its difference in strength from the standard was not plainly stated on its label. The article was alleged to be misbranded in that the statement "Zinc Oxide Ointment U. S. P.," appearing on its label, was false and misleading.

The ammoniated mercury ointment was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, but its strength differed from the standard set forth therein since the compendium provides that ammoniated mercury ointment shall contain an amount of ammoniated mercury corresponding to not more than 4.5 percent of Hg. (mercury), whereas the article contained ammoniated mercury corresponding to amounts of mercury varying from 8.32 percent to 8.39 percent, and its difference in strength from the standard was not plainly stated on its label. The article was alleged to be misbranded in that the statement "Ammoniated Mercury Ointment * * * U. S. P.," borne on its labels, was false and misleading.

The carbolic ointment was alleged to be adulterated in that it purported to be and was represented as a drug the name of which, "Phenol Ointment" or "Ointment of Carbolic Acid," is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from or its quality fell below the standard set forth therein since the compendium provides that phenol ointment or ointment of carbolic acid shall contain not less than 1.8 percent of carbolic acid, whereas the article contained carbolic acid in amounts varying from 1.56 percent to 1.69 percent, and its difference in strength and quality from the standard was not plainly stated on its label. It was alleged to be misbranded in that the statements "Carbolic Ointment U. S. P.," and "Net Wgt. 1 Oz.," borne on its labels, were false and misleading since the article did not conform with the requirements of the Pharmacopoeia, and its containers did not contain 1 ounce net weight of the article but contained a smaller amount.

On June 26, 1944, a plea of guilty having been entered on behalf of the defendant, the court imposed a fine of $200 on each of 6 counts. Payment of the fine on 5 of the counts was suspended.

1212. Adulteration of digitalis tablets and tincture of digitalis. U. S. v. Direct Sales Co., Inc. Plea of guilty. Fine, $300. (F. D. C. No. 11336. Sample Nos. 21817–F, 21818–F.)

On January 24, 1944, the United States attorney for the Western District of New York filed an information against the Direct Sales Co., Inc., Buffalo, N. Y., alleging shipment of a quantity of the above-named products on or about January 19, 1943, from the State of New York into the State of Pennsylvania.

The digitalis tablets were alleged to be adulterated in that each tablet purported and was represented to possess a potency equivalent to not more than 0.62 digitalis unit, as defined in the United States Pharmacopoeia, whereas each tablet possessed a potency equivalent to not less than 1.35 digitalis units.

The tincture of digitalis was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from the official standard since 1 cc. of the article possessed a potency equivalent to not less than 1.86 U. S. P. digitalis units, which is 86 percent in excess of the potency of the official product, and its difference in strength was not plainly stated on its label.

On February 14, 1944, a plea of guilty having been entered on behalf of the defendant, the court imposed a fine of $150 on each of 2 counts, a total fine of $300.

1213. Adulteration of Bevitin (thiamine hydrochloride). U. S. v. 3,000 Ampuls and 12,000 Ampuls of Bevitin Brand of Thiamine Hydrochloride. Decrees of condemnation. Portion of product ordered released under bond; remainder ordered destroyed. (F. D. C. Nos. 11289, 11290. Sample Nos. 29634–F, 29635–F.)

On December 9 and 20, 1943, the United States attorneys for the Eastern District of Missouri and the Southern District of Georgia filed libels against 3,000 ampuls of the above-named product at St. Louis, Mo., and 12,000 ampuls of the same product at Savannah, Ga., alleging that the article had been shipped on or about November 3, 1943, from Brooklyn, N. Y., by the Pro-Medico Laboratories, Inc.; and charging that it was adulterated.

The article was alleged to be adulterated in that its purity and quality fell below that which it purported and was represented to possess, i. e., "Intravenous—Intramuscular," since it was not suitable for parenteral use because of contamination with undissolved material.

On February 24 and March 4, 1944, the Pro-Medico Laboratories, Inc., having appeared as claimant for the Georgia lot and having admitted the allegations of the libel, and no claimant having appeared for the Missouri lot, judgments of condemnation were entered and the Georgia lot was ordered released under bond to be brought into compliance with the law under the supervision of the Food and Drug Administration, and the Missouri lot was ordered destroyed.

1214. Adulteration of suprarenalin solution. U. S. v. 432 Vials of Suprarenalin Solution. Default decree of condemnation and destruction. (F. D. C. No. 11519. Sample No. 65902–F.)

On January 3, 1944, the United States attorney for the Southern District of New York filed a libel against 432 vials of suprarenalin solution at New York, N. Y., alleging that the article had been shipped on or about November 12 and 26, 1943, by the Armour Laboratories, Chicago, Ill.; and charging that it was adulterated. The article was labeled in part: "Suprarenalin Solution 1 : 1,000 A brand of solution of epinephrine hydrochloride U. S. P. Sterile—For Hypodermatic Use."

The article was alleged to be adulterated in that it purported to be and was represented as a drug, epinephrine hydrochloride ampuls, the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth therein since the article was not free from undissolved material.

On February 28, 1944, no claimant having appeared, judgment of condemnation was entered and it was ordered that a portion of the product be released to the Federal Security Agency, and that the remainder be destroyed.

1215. Adulteration of pentothal sodium with redistilled water. U. S. v. 1,866 Packages of Pentothal Sodium with Redistilled Water. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 11264. Sample No. 57293–F.)

On December 11, 1943, the United States attorney for the Northern District of New York filed a libel against 1,866 packages of the above-named product at Schenectady, N. Y., alleging that the article had been shipped on or about November 12, 1943, from Chicago, Ill., by the Abbott Laboratories; and charging that it was adulterated. The article was labeled in part: "Pentothal Sodium * * * And Chemically Pure Water, 50 CC. * * * Dissolve the contents of the ampoule of Pentothal Sodium in the 50 cc. of sterile chemically pure water * * * For intravenous injection." The ampul of water was labeled "Chemically Pure Water (Ampul of Redistilled Water, N. F.)."

The article was alleged to be adulterated in that the water purported to be and was represented as redistilled water, a drug the name of which is recognized in the National Formulary, an official compendium, but its quality and purity fell below the standard set forth therein since the water was not free from undissolved material.

On March 15, 1944, the Abbott Laboratories, claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond to be brought into compliance with the law, under the supervision of the Food and Drug Administration.

1216. Adulteration of atabrine and distilled water combination packages. U. S. v. 1,050 Cartons and 2,473 Cartons of Atabrine Dihydrochloride with Distilled Water. Decrees of condemnation. Portion of product ordered released under bond; remainder ordered destroyed. (F. D. C. Nos. 11799, 11800. Sample Nos. 10695–F, 12665–F.)

On February 11 and 21, 1944, the United States attorneys for the Northern District of California and the Western District of Washington filed libels against 3,523 cartons of the above-named product at Oakland, Calif., and Seattle, Wash., respectively, alleging that the article had been shipped on or about December 17 and 23, 1943, from Albany, N. Y., by the Winthrop Chemical Co., Inc.; and charging that it was adulterated. The article was labeled in part: (Carton) "5 Ampuls 0.2 Gm. Atabrine Dihydrochloride * * * With 5 Ampuls, 10 cc. Size Sterile Distilled Water."

The article was alleged to be adulterated in that it purported to be and was represented as a drug, "Sterilized Distilled Water" and "Water for Injection," the names of which are recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth therein since the Pharmacopoeia provides that sterilized distilled water (and water for injection) is a clear liquid, whereas the article was contaminated with undissolved material.

On March 17, 1944, the Winthrop Chemical Co., Inc., having appeared as claimant for the California lot, judgment of condemnation was entered and the product was ordered released under bond to be brought into compliance with the law, under the supervision of the Food and Drug Administration. On August 19, 1944, no claimant having appeared for the Seattle lot, judgment of condemnation was entered and the product was ordered destroyed.

1217. Adulteration of sterile distilled water. U. S. v. 2 Packages and 10 Packages of Sterile Distilled Water. Default decree of condemnation and destruction. (F. D. C. No. 11685. Sample No. 51270–F.)

On January 24, 1944, the United States attorney for the District of Massachusetts filed a libel against 2 packages, each containing 25 ampuls, and 10 packages, each containing 10 ampuls, of the above-named product at Worcester, Mass., alleging that the article had been shipped on or about August 12, 1943, from Philadelphia, Pa., by the Stratford-Cookson Co.; and charging that it was adulterated.

The article was alleged to be adulterated in that it purported to be and was represented as a drug, "Sterilized Distilled Water" and "Water for Injection," the names of which are recognized in the United States Pharmacopoeia, and official compendium, and as "Ampuls of Redistilled Water," a drug the name of which is recognized in the National Formulary, an official compendium, but its quality and purity fell below the standard set forth in those compendiums since it was contaminated with undissolved material.

On March 6, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1218. Adulteration of cream of tartar. U. S. v. 5 Drums of Cream of Tartar. Default decree of condemnation and destruction. (F. D. C. No. 10965. Sample No. 50607–F.)

On October 18, 1943, the United States attorney for the Eastern District of Pennsylvania filed a libel against 5 drums of cream of tartar at Philadelphia, Pa., alleging that the article had been shipped on or about April 17, 1943, from New York, N. Y., by the Legion Products Co.; and charging that it was adulterated. The article was labeled in part: "Cream of Tartar Mfd. By the Brocker Chemical Co. Morganville, N. J."

A portion of the article (4 drums) was of a light brown color and was not completely soluble in ammonia, whereas the United States Pharmacopoeia provides that cream of tartar shall be a white powder, and that 0.5 gram shall be completely soluble in 3 cc. of ammonia test solution. Examination of the fifth drum showed that it contained a mixture of sodium bicarbonate and tartaric acid instead of cream of tartar.

The article was alleged to be adulterated (four drums) in that it was represented as a drug the name of which is recognized in an official compendium, the United States Pharmacopoeia, but its quality and purity fell below the standard set forth therein; and (one drum) in that a mixture of sodium bicarbonate and tartaric acid had been substituted wholly for cream of tartar.

The article in one drum was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

On February 21, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered sold. On May 15, 1944, the decree was amended to provide for the destruction of the product.

1219. Adulteration and misbranding of chloroform. U. S. v. 2,000 Cartons, 1,000 Cartons, and 1,000 Cartons of Chloroform. Decrees of condemnation. Product ordered released under bond. (F. D. C. Nos. 11192, 11220, 11448. Sample Nos. 29638–F, 48151–F, 49475–F, 49476–F, 54730–F, 54731–F.)

On or about December 1, 11, and 30, 1943, the United States attorney for the Western District of Kentucky filed libels against 4,000 cartons, each containing 12 ampuls, of chloroform at Louisville, Ky., alleging that the article had been shipped from on or about November 12 to December 11, 1943, by Parke, Davis and Co., from Detroit, Mich.; and charging that it was adulterated and that a portion was misbranded.

Examination of samples revealed that 20 cc. of the article required from 0.38 to 40.0 cc. of hundredth-normal sodium hydroxide for neutralization, whereas the United States Pharmacopoeia, in establishing the limit for the content of acids and phosgene in chloroform, provides that not more than 0.20 cc. of hundredth-normal sodium hydroxide is required to neutralize 20 cc. of chloroform.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the stand ard set forth therein since the article failed to meet the requirement for acids and phosgene specified for chloroform by the Pharmacopoeia.

A portion of the article was alleged to be misbranded in that the statements in the labeling, "the purest chloroform obtainable, free from decomposition products," and "Dropper-Ampoules of Chloroform insure for every operation an ample supply of anesthetic of full strength and purity," were false and misleading as applied to an article which failed to meet the requirements of the Pharmacopoeia for quality and purity.

On June 13, 1944, Parke, Davis and Co. having appeared as claimant, judgments of condemnation were entered and the product was ordered released under bond, conditioned that it should not be sold as an anesthetic and that it be disposed of in compliance with the law, under the supervision of the Food and Drug Administration.

1220. Adulteration and misbranding of chloroform. U. S. v. 1 Drum of Chloroform. Default decree of condemnation and destruction. (F. D. C. No. 11305. Sample No. 44391–F.)

On December 15, 1943, the United States attorney for the Southern District of New York filed a libel against 1 drum containing approximately 300 pounds of chloroform at New York, N. Y., alleging that the article had been shipped on or about October 15, 1943, by the City Chemical Corporation, Jersey City, N. J.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth therein since it was not a clear liquid but contained many visible black particles in suspension, the residue was greater than that permitted by the test for residue laid down in the Pharmacopoeia, the carbonizable substances exceeded those permitted by the Pharmacopoeia, and the article contained quantities of odorous and chlorinated decomposition products in excess of those permitted by the Pharmacopoeia.

The article was alleged to be misbranded in that the statement "Chloroform U. S. P.," appearing on the drum, was false and misleading as applied to an article that did not comply with the requirements of the United States Pharmacopoeia.

On January 5, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1221. Adulteration and misbranding of ammonium chloride. U. S. v. 2 Barrels of Ammonium Chloride. Default decree of condemnation and destruction. (F. D. C. No. 11234. Sample No. 34596–F.)

On or about December 11, 1943, the United States attorney for the Southern District of Florida filed a libel against 2 barrels of ammonium chloride at Jacksonville, Fla., alleging that the article had been shipped on or about September 16, 1943, from Brooklyn, N. Y., by the New York Quinine and Chemical Works; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that it was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth therein since a bluing, such as Turnbull's blue and Prussian blue, had been admixed with the article.

The article was alleged to be misbranded in that the statements appearing in its labeling, "Ammonium Chloride U. S. P.," and "Ammonium Chloride U S P Grade," were false and misleading as applied to ammonium chloride with which bluing had been admixed.

On February 2, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1222. Adulteration and misbranding of mercurin suppositories. U. S. v. 98 Cartons and 151 Cartons of Mercurin Suppositories. Default decrees of condemnation and destruction. (F. D. C. Nos. 9557, 9956. Sample Nos. 11780–F, 15007–F.)

On May 19, 1943, the United States attorneys for the Northern and Southern Districts of California filed libels against 98 cartons and 151 cartons of mercurin suppositories at San Francisco and Los Angeles, Calif., respectively, alleging that the article had been shipped from New York, N. Y., by Campbell Products, Inc., between the approximate dates of October 13 and December 14, 1942; and charging that it was adulterated and misbranded.

Examination disclosed that the article contained globules of metallic mercury, and that one portion also contained approximately 30 milligrams per suppository of mercury in an ionizable form.

The article was alleged to be adulterated in that its purity fell below that which it purported and was represented to possess since its label indicated that its mercury content was in combination as beta-methoxy-gamma-hydroxy mercuripropylamide of camphoric acid sodium salt and in non-ionizable form, when in fact it was present in part as the uncombined metal and also, in a portion, in ionizable form.

It was alleged to be misbranded in that the statement on the label declaring that "Each Suppository Contains 0.5 Gram-Beta-Methoxy-Gamma-Hydroxy Mercuripropylamide of Camphoric Acid Sodium Salt * * * Equivalent to 0.2 Gram of Mercury in Non-Ionizable Form" was false and misleading as applied to the article.

On June 14 and July 5, 1943, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

1223. Adulteration and misbranding of lubricating jelly. U. S. v. 1,120 Tubes of Lubricating Jelly (and 11 other seizure actions against lubricating jelly.) Decrees of condemnation. Portion of product ordered released under bond; remainder ordered destroyed. (F. D. C. Nos. 8574, 8632, 8718, 8728, 8917, 8964, 9018, 9064, 9139, 9175, 9220, 9221. Sample Nos. 189–F, 301–F, 5574–F, 13164–F, 13171–F, 18376–F, 25108–F, 25156–F, 25411–F, 25564–F, 29459–F, 29465–F, 31374–F, 32234–F, 32240–F, 32315–F.)

This product was contaminated with living micro-organisms.

Between October 15, 1942, and January 23, 1943, the United States attorneys for the Eastern District of Virginia, the Southern District of Georgia, the Southern District of Ohio, the Western District of Washington, the Northern District of Illinois, and the Northern District of New York filed libels against the following quantities of lubricating jelly: 1,744 tubes and 480 packages at Richmond, Va.; 9,684 tubes at Columbus, Ohio; 1,374 tubes at Savannah, Ga.; 2,822 tubes at Seattle, Wash.; 633 tubes at Chicago, Ill.; and 890 packages at Binghamton, N. Y. It was alleged that the article had been shipped within the period from on or about May 26 to December 3, 1942, from Boston, Mass., by the United Drug Co., with the exception of two lots (480 packages at Richmond, and 1,800 tubes at Seattle) which were alleged to have been shipped by the Columbus Quartermaster Depot, from Columbus, Ohio. The article was labeled in part: "Lubricating Jelly Sterile."

The article was alleged to be adulterated in that its purity and quality fell below that which it purported and was represented to possess, i. e., "Sterile."

It was alleged to be misbranded in that the statements in its labeling which represented that the article was sterile were misleading since it was not sterile but was contaminated with living micro-organisms.

On April 6, 1943, the United Drug Co., claimant for the lots of 5,000 tubes and 4,408 tubes at Columbus, having admitted the allegations of the libels against those lots, judgments of condemnation were entered and thev were ordered released under bond for resterilization under the supervision of the Food and Drug Administration. Between December 21, 1942, and September 16, 1943, no claimant having appeared for the other lots, judgments of condemnation were entered and they were ordered destroyed.

1224. Adulteration and misbranding of first aid kits. U. S. v. 69 Packages of First Aid Kits. Default decree of condemnation and destruction. (F. D. C. No. 11604. Sample No. 54408–F.)

On January 15, 1944, the United States attorney for the Northern District of Illinois filed a libel against 69 packages of first aid kits at Chicago, Ill., alleging that the article had been shipped on or about October 18, 1943, by the Gus. J. Schaffner Co., from Avalon, Pittsburgh, Pa.; and charging that it was adulterated and misbranded. The article was labeled in part: "Schaffner's 'Little Doc' Jr. First Aid Kit."

The first aid kit contained, among other things, absorbent cotton labeled, (carton) "Schaffner's 'Little Doc' White Absorbent Cotton Sterilized After Packing." Examination showed that the absorbent cotton was not sterile, as required by the United States Pharmacopoeia.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in an official compendium, and its quality and purity fell below the standard set forth therein.

It was alleged to be misbranded in that the statements in the labeling, "Sterilized Absorbent Cotton Your First Line of Defense Against Infection," and "Sterilized After Packing," were false and misleading since the cotton contained in the article was not sterile, and unsterile cotton is not the first line of defense against infection.

On March 9, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1225. Adulteration and misbranding of first aid dressings and misbranding of bandage compresses. U. S. v. 104 Cases of First Aid Dressings (and 2 other seizure actions against bandage compresses). Decrees of condemnation. Product ordered released under bond with the exception of 1 lot of bandage compresses, which was ordered destroyed. (F. D. C. Nos. 11174, 12440, 12845. Sample Nos. 49474–F, 58686–F, 60765–F.)

Between November 20, 1943, and July 3, 1944, the United States attorneys for the Western District of Kentucky, the Eastern District of Virginia, and the Northern District of California filed libels against 104 cases, each containing 500

first aid dressings, at Louisville, Ky., 12,000 bandage compresses at Richmond, Va., and 20,000 cartons, each containing 4 bandage compresses, at San Francisco, Calif., alleging that the articles had been shipped from Worcester, Mass., by the Handy Pad Supply Co., on or about July 22, 1943, and March 9 and April 25, 1944; and charging that the articles were misbranded and that the first aid dressings were also adulterated. The articles were labeled in part: "Small First Aid Dressing U. S. Army Carlisle Model Sterilized," and "Bandage Compresses Dyed Dressings Sterilized."

The first aid dressings were alleged to be adulterated in that the purity and quality of the article fell below that which it purported and was represented to possess, i. e., "Sterilized." The article was alleged to be misbranded in that the statements appearing on its labels, "Sterilized," and "Sterilized. Red Color indicates back of dressing. Put other side next to wound," were false and misleading when applied to the article, which was not sterile but was contaminated with living micro-organisms.

The bandage compresses were alleged to be misbranded in that the statement on their label, "Sterilized," was false and misleading as applied to the bandages, which were not sterile but were contaminated with living micro-organisms.

On February 26 and September 11, 1944, Albert H. Tessier, doing business as the Handy Pad Supply Co., having appeared as claimant for the Kentucky and California lots, judgments of condemnation were entered and the products were ordered released under bond to be resterilized under the supervision of the Food and Drug Administration. On June 17, 1944, no claimant having appeared for the Virginia lot, judgment of condemnation was entered and the product was ordered destroyed.

1226. Adulteration and misbranding of gauze pads. U. S. v. 19 Packages of Gauze Pads. Default decree of condemnation and destruction. (F. D. C. No. 11630. Sample No. 49793–F.)

On January 12, 1944, the United States attorney for the Western District of New York filed a libel against 19 packages of gauze pads at Buffalo, N. Y., alleging that the article had been shipped on or about May 25, 1943, from Worcester, Mass., by the Handy Pad Supply Co.; and charging that it was adulterated and misbranded. The article was labeled in part: (Package) "100 J–F Gauze Pads."

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth therein since it was not sterile.

The article was alleged to be misbranded in that the statement in its labeling, "Sterilized After Packaging," was false and misleading as applied to the article, which was not sterile but was contaminated with viable spore-bearing rods or cocci.

On February 9, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1227. Adulteration and misbranding of sutures. U. S. v. 2,868 Tubes, 2,868 Tubes and 2,868 Tubes of Sutures. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 8876. Sample No. 32806–F.)

On November 17, 1942, the United States attorney for the Northern District of New York filed a liable against 8,604 tubes of sutures at Binghamton, N. Y., alleging that the article had been shipped on or about September 17, 1942, from Boston, Mass., by the Flanders-Day Co.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth therein since it did not meet the tests for sterility of solids as required by that text but was contaminated with living micro-organisms.

The article was alleged to be misbranded in that the statement on its label, "U. S. P. Surgical Catgut Sutures Sterile," was false and misleading.

On January 8, 1943, the Flanders-Day Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for resterilization under the supervision of the Food and Drug Administration.

1228. Adulteration and misbranding of prophylactics. U. S. v. 15 Gross and 4½ Gross of Prophylactics. Decrees of destruction. (F. D. C. Nos. 11186, 11253. Sample Nos. 40792–F, 43852–F.)

On November 26 and December 8, 1943, the United States attorneys for the Western District of Missouri and the District of Minnesota filed libels against 15 gross of prophylactics at Kansas City, Mo., and 4½ gross of the same product at Minneapolis, Minn., alleging that the article had been shipped on or about November 11 and 13, 1943, from Chicago, Ill., by F. G. Karg; and charging that it was adulterated and that the lot at Minneapolis was also misbranded. A portion of the article was labeled in part: "Kargston Aquapac."

The article was alleged to be adulterated in that its quality fell below that which it purported or was represented to possess since it contained holes.

The Minneapolis lot was alleged to be misbranded in that the statement on the unit package, "For Protection Against the Communication of Disease," was false and misleading since the article would not be effective as a prophylactic because of the presence of holes.

On January 29 and February 8, 1944, no claimant having appeared, judgments were entered ordering that the product be destroyed.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

DRUGS FOR HUMAN USE

1229. Misbranding of Stumicaid. U. S. v. Vernon F. Hoobler (Hoobler & Hazel Laboratory). Plea of guilty. Fine, $500 and costs. (F. D. C. No. 10626. Sample No. 22078–F.)

On January 18, 1944, the United States attorney for the Northern District of Ohio filed an information against Vernon F. Hoobler, trading as the Hoobler & Hazel Laboratory, Dalton, Ohio, alleging shipment of a quantity of Stumicaid, on or about February 25, 1943, from the State of Ohio into the State of Pennsylvania.

Analysis disclosed that the article consisted of yellowish-white, horny masses, consisting chiefly of organic protein material, with a small amount of plant material, including anise and a laxative drug such as senna.

The article was alleged to be misbranded because of false and misleading statements appearing in its labeling which represented and suggested that it would be efficacious in the cure, mitigation, treatment, or prevention of stomach trouble; that it would help restore the stomach to a normal condition; that it would be efficacious in the treatment of unusual distress, sick stomach, vomiting, and similar conditions indicated by the abbreviation "etc.," gas pains after eating, belching, bloating, heartburn, pimples, nervous stomach, stomach ulcers, too much acid and the effect of over-indulgence, stomach disorders developed over a long period of time, stomach trouble in adults and children, and nervous, jittery, or jumpy stomach; that it was an excellent remedy for most stomach ailments; that it would aid nature in renewing the stomach lining; and that it would be efficacious in the correction of automobile, train, or boat sickness, and cankerous sores of the mouth.

It was alleged to be further misbranded (1) in that the statement on its label, "Contents Pure Organic Elements of Ingluvin and Herbs," was false and misleading since the article did not consist of ingluvin and herbs, but did consist essentially of gizzard linings, anise, and compound senna powder; (2) in that the name "Stumicaid" was false and misleading since the article would not aid the stomach; and (3) in that the label of the article bore no statement of the quantity of the contents.

On March 1, 1944, the defendant having entered a plea of guilty, the court imposed a fine of $500 and costs.

1230. Misbranding of Nulfey Tablets, O. B. C. Capsules, Medrex Ointment, and Medrex Soap. U. S. v. Martin A. Levitt (William A. Reed Co.). Plea of nolo contendere. Fine, $500. (F. D. C. No. 11365. Sample Nos. 22654–F, 22655–F, 22867–F, 44456–F, 44457–F.)

On May 23, 1944, the United States attorney for the Eastern District of Pennsylvania filed an information against Martin A. Levitt, an individual trading as the William A. Reed Co., Philadelphia, Pa., alleging shipment from on or about April 7 to June 30, 1943, from the State of Pennsylvania into the States of New Jersey, Delaware, and New York of quantities of the above-named products.

*See also Nos. 1201–1205, 1207–1212, 1219–1228.

Analysis of the Nulfey Tablets disclosed that they consisted essentially of sodium salicylate, sodium biphosphate, methenamine and plant drugs including a laxative plant drug. The article was alleged to be misbranded because of false and misleading statements in the labeling which represented and suggested that it would be efficacious in the cure, mitigation, treatment, or prevention of rheumatism, arthritis, neuritis, sciatica and kidney dysfunction; and that diuretics and analgesics are efficacious in the cure, mitigation, treatment, or prevention of kidney dysfunction.

Analysis of the O. B. C. Capsules disclosed that they consisted essentially of phenolphthalein, caffeine, and clay. The article was alleged to be misbranded because of false and misleading statements in the labeling which represented and suggested that it would be efficacious in the treatment of obesity.

Analysis disclosed that the Medrex Ointment consisted essentially of zinc oxide and petrolatum with small amounts of acetanilid, starch, methyl salicylate, benzoic acid, carbolic acid, and salicylic acid. The article was alleged to be misbranded because of false and misleading statements in the labeling which represented and suggested that it would be efficacious in the cure, mitigation, treatment, or prevention of the itching and irritation accompanying eczema; and that, when used alone or in conjunction with Medrex Soap, it would be efficacious in the cure, mitigation, treatment, or prevention of eczema, pimples, skin blotches, and surface skin conditions.

Analysis of the Medrex Soap disclosed that it was a soap containing small amounts of a zinc compound, starch, and salicylic acid. The article was alleged to be misbranded because of false and misleading statements in the labeling which represented and suggested that, when used alone or in conjunction with the Medrex Ointment, it would be efficacious in the cure, mitigation, treatment, or prevention of eczema, pimples, skin blotches, and surface skin conditions.

On May 23, 1944, a plea of nolo contendere having been entered by the defendant, the court imposed a fine of $100 on each of 5 counts, a total fine of $500.

1231. Misbranding of "666." U. S. v. 70½ Dozen Bottles and 76½ Dozen Bottles of "666." Tried to a jury. Verdict for the Government. Decree of condemnation and destruction. (F. D. C. Nos. 10914 to 10916, incl., 11043 to 11045, incl. Sample Nos. 35187–F, 35189–F, 35623–F, 35851 to 35853–F, incl.)

On October 12 and November 3, 1943, the United States attorney for the Middle District of Georgia filed libels against a total of 147 dozen bottles of "666" at Valdosta, Ga., alleging that the article had been shipped between the approximate dates of March 31 and October 21, 1943, from Jacksonville, Fla., by the Monticello Drug Co.; and charging that it was misbranded. On February 22 and March 20, 1944, the libels were amended.

Examination of samples disclosed that the article contained as medicinal ingredients antipyrine (an analgesic drug), ammonium chloride, and Epsom salt; and that it contained no quinine or other ingredient useful in the treatment of malaria. The article was colored yellow with a coal-tar dye, in simulation of a drug of similar appearance and packaging which contained quinine sulfate and which was previously marketed by the Monticello Drug Company for the treatment of malaria.

The article was alleged to be misbranded (1) in that the bottle, the bottle top, the color and appearance of the article, the price, and the labels and cartons with the numerals "666" printed in red color on the yellow background, and with the other portions of the label and carton in yellow, red, and black, were misleading since in combination they constituted a statement and device which created in the minds of purchasers the impression and belief that the article was the product which had been formerly for many years advertised and sold as a treatment for malaria; (2) in that the article was an imitation of the former product; and (3) in that it was offered for sale under the name of another drug, the former product.

On March 20, 1944, the Monticello Drug Co., claimant, filed exceptions to the amended libels on the ground that there was no authority for the seizure of the product since its label clearly stated the active ingredients and did not mention that it was an antimalarial preparation. The claimant's motion to sustain those exceptions was denied by the court. On March 27, 1944, the claimant having filed answers to the libels, denying that the product was misbranded, and the libels having been consolidated, the case came on for trial before a jury. The taking of testimony was concluded on March 29, 1944, on which date the court delivered the following instructions to the jury:

DEAVER, *District Judge:* "Gentlemen of the jury, an act of Congress known to some of us as the Pure Food and Drug Act, prohibits the shipment in interstate commerce of any drug—of course, there are a great many other things in the Act

but I am confining it here to drugs because that is all we are interested in here—which is misbranded; and then the Act goes on to define the meaning of mis-brand and it says that a drug is misbranded if the label is misleading. That is one instance in which it is misbranded. Then, it is misbranded if the container of the drug is so made or filled as to be misleading. Then, another instance of misbranding is if a drug is an imitation of another drug. And another is, that if a drug is offered for sale under the name of another drug. The whole act is designed to protect the public, so that the public will not be buying one thing, thinking that they are buying another thing.

"Now here the libel, as it is called—the paper filed by the government as a suit—alleges that this product which you have heard about here, the new product, is a misbranded drug; that there is and has been, the Government contends through a long number of years a product known and advertised to the public and well known to the public as three sixes or six hundred and sixty six or 666, and that the general buying public have become acquainted with that product, whatever it is. They contend, as a matter of fact, that it contained quinine and iron and that the new product does not contain either; but the government contends that inasmuch as the old product of 666 containing iron and quinine was well known to the public and had been for years and years, that this product, this new product which does not contain iron or quinine, would under the circumstances which you have heard outlined in the evidence, the government contends, cause the general public to buy this new product, thinking they were obtaining the old product. In general, that is the contention.

"The Monticello Drug Company comes into the case—of course, this case originated by the seizure of certain bottles of this product by the government and then this paper that I referred to, called a libel, which is a paper asking the court to condemn the seized product, it is really a proceeding against the product iself, but under the law the interested party, that is the Monticello Drug Company, has a right to come into the case and defend. The papers, if you want to look at them, denominate the Monticello Drug Company as the intervenor and in some cases as the claimant, that is the claimant of the product seized—But in any event, the Monticello Drug Company came into the case, as it had a right to do, and defends against the condemnation of this seized product, and that is the issue. The issue is between the government and the Monticello Drug Company as to whether this product is under the circumstances misbranded or not in any of the respects which I mentioned.

"Now, the question is to be decided by this jury and you are to decide the case from a preponderance of the evidence in the case. A preponderance of the evidence is just that greater weight of the evidence which inclines the mind of a reasonable man to one side of an issue rather than to the other side. The burden is on the government to show that this new product, which has been seized, is misbranded in at least some one of these respects which I have mentioned. You will apply the evidence to the law, as I have stated it in these various respects, and say whether, in your opinion, the evidence does show that the product was misbranded in any one of these different ways.

"Now, the first way I mentioned to you is that it is misbranded if the label is misleading. Well, I want to make that division of the suit clear to you. I may state to you, I think, that if a purchaser or anybody else of average intelligence should actually take the label on the new product and read it, that the label in and of itself and without more would not be misleading because the label itself does state what the drug contains. But the government goes further on other grounds and says that the drug is misbranded in that the method in which it is dressed up, the container, the box or paper carton. whatever you want to call it, is so colored and so designed with the figures 666, and the color of the product and the well known former product of 666, that all of those things taken together would mislead the average member of the public who calls for 666 in any store where it is available.

"Now, before I elaborate at all on these, I think that inasmuch as the evidence has taken a very wide latitude and certainly the arguments of counsel on both sides have taken a very wide latitude, I conceive it to be my duty under those circumstances to try to put before this jury exactly what it is you are to pass on.

"A great many things have been argued here in this case on both sides that haven't really got anything to do with the question that you are to decide. Of course, it is properly a matter of the history of the case here to show that when the war came along and quinine had to be restricted for military use, except in malaria, and that a certificate had to be had before it could be sold for malaria, that is all properly before you, but that is not the question that you are to decide;

and the question moreover is not whether the wholesale druggist and retail druggist were advised that a change had been made. That is not the point in the case either. There is evidence here that the Monticello Drug Company did inform certainly a large part, if not all, of the wholesale druggists and the retail druggists that a change had been made in this product and specifically called their attention to it. But that is not the question that you are to decide, whether a wholesale druggist or the retail druggist knew about it. If they didn't, they might be innocent of selling something that was not what they thought it was, of if they did know the difference and sold it nevertheless without complying with the law, why some of the druggists might be guilty, but that is not the question for you to decide here. We are dealing here with the question of, not whether the wholesale druggist was misled, not whether the retail druggist was misled, we are dealing here with whether under all the facts and circumstances an average member of the buying public who was not informed would be misled by the way this product is gotten up and handled.

"Something was said too here in argument—and that is the only reason that I mention it—that if you were to find in favor of the government and against the Monticello Drug Company, that would prevent the Monticello Drug Company from using their trade name, 666. Well, I didn't stop counsel in the argument because I intended at least to try to make it clear to the jury. Your finding, no matter which way it is, will not prevent the Monticello Drug Company from using its trade name 666. No attack is made in this case on that trade-mark and certainly the old product of 666, when the war is over and the ingredients can be obtained for that product, can be manufactured and again put on the market for people with malaria or anything else as for that matter they want to buy it for. There is no reason, so far as your verdict is concerned, why they can't continue to do that right on. The effect of an adverse verdict against the Monticello Drug Company, so far as this suit is concerned would be that it would prevent the Monticello Drug Company from putting out and selling to the public this new product under the name, if you find that is true, 666, which would mislead the buying public into thinking they were buying the old product. If you found a verdict against the Monticello Drug Company, then they could not keep on putting up this new product in the same form and with the same lettering and with the same figures and under the same circumstances that we have heard about in this case. They could not keep on doing that but the government contends that that is the very thing that they ought not to do, is to put this product on the public under circumstances which would lead the public to believe that it is the old 666.

"And then too, if I am wrong the Food and Drug agents here can correct me, but if you find a verdict against this product or against the claimant to it, then, as has been done in numerous other cases where the product itself is not in and of itself objectionable, it would not necessarily have to be destroyed or withdrawn and not used or lost utterly. I know that in a great many food cases and drug cases this is the result, that if you have a food case and the food is rotten or poison or unfit for use for any purpose, then, of course, it is destroyed, where it is condemned. It is destroyed because it is not fit for use and can't be used for any purpose; but if some food product is shipped in violation of the Food and Drug Act, but nevertheless may be properly used for some purpose in some other way, then by an arrangement and under the supervision of the Food and Drug people, the owner or the claimant of such food as that would be permitted to rework it, so to speak, under the supervision of the Food and Drug Agency; and if it could be used for some proper purpose, than the Food and Drug agent would cooperate in reworking or supervising the reworking just to see that it is properly used.

"So, in this case, so far as this suit is concerned, no attack has been made on this new product itself as a cold remedy or for any purpose as for that matter. No attack has been made on the drug itself. It may or may not have proper uses; we just don't know anything about that and not particularly concerned with it. It may be a product that could be used and it might be a good product, but the question here is not whether it is a good product or not. That is not the question at all. But if it is a good product, then the effect of your verdict would be to prohibit the sale of it in this present form. If you think it would mislead the public, then your verdict against the Monticello Drug Company would prevent them from selling this package that you have seen here in its present form and with its present coloring just as it stands now, would prevent them from selling that under this name 666 because your verdict would mean that you think that the sale of it with its present get-up, dressing, boxing and present coloring in connection with the previous reputation of the old product and all the other facts and circumstances in this case, your verdict would mean that you think that to

sell that product now under that name and style and get-up would mislead members of the buying public; and if you found such a verdict, it would prevent the Monticello Drug Company from continuing to sell it in that present form, and so far as I know, that is the only effect your verdict would have, except of course to destroy these bottles that have been seized, if the Monticello Drug Company did not ask to have them returned and re-worked and sold in some way or other that would not be misleading. But I know of no reason why they could not take all of this product that is bottled at present in that form, why they couldn't take that back and put the same product out under some form or other that would not be misleading.

"Now, gentlemen, the question is for you to decide and you are to decide it from what you have heard in the evidence itself. You are the sole judges of what the evidence shows. I could review the testimony on both sides and I could even tell you what I think about it; I could express an opinion about what I think about it under the practice in this court but I doubt if that would be helpful because, after all, even if I did, you would not be bound by any opinion that I might have about the evidence. The law provides that you should accept without question the law that I give you, that whatever I tell you is the law, you are supposed to take that; but so far as the facts are concerned, you are not bound by anybody's opinion, including my own. If I should express one—as a matter of fact, I am not going to express one, I don't think it would be helpful at all—but you are to decide whether this product here, this new product is misbranded in any of the respects contended by the government.

"Now, if you think, under the second section that I stated to you in the beginning, if you think that the container of this new product is so made in size and color, lettering and figures, that it is so made and the container so filled and colored, in connection with whatever reputation you may think the old product previously had, if you think that because of the container fixed up as it is and the product colored as it is, in view of the impression which the public has heretofore had of the original 666, if you think under all the circumstances that this product, if put out to the public, would be misleading, then you would find in favor of the government, because that would mean that this product here, under the definition which I have given you and which is in the statute itself, would be misleading.

"Or, if you think that this new product, because of the way it is handled and bottled and dressed up and colored, if you think that the new product is being offered for sale or sold to the public in imitation, as just a drug in imitation of the old original 666, but is not the old 666; in other words, if you think that the new drug is just an imitation of the old 666 and under all the facts and circumstances that it is not the old 666 but is an imitation of the old 666, then it would be misbranded under this act.

"Or, somewhat similarly, that if it is offered for sale under the name of another drug. You see the second thing that I mentioned to you there was if it is an imitation of another drug. Now, this one is slightly different. It says that if it is offered for sale in the name or under the name of another drug. Now, that would mean that if you think that this product, this new product, is not the same as the old original 666, but that it is being offered for sale to the public under the name of the old original 666, then it would be offered for sale, one drug would be offered for sale under the name of another drug, and if that is in your mind, under all the circumstances, likely to mislead the average member of the buying general public who buy this medicine, if you think from all the circumstances you have heard in this case, that the average member of the buying public who go to stores and call for this medicine 666 would likely be mislead into accepting the new product under the impression that they were obtaining the old product, that would amount to misbranding and you would find then in favor of the government.

Now, of course, the question here is not a question of whether it would be harmful financially to the MonticelloDrug Company. Whether it would entail a loss, of course, I do not know about that and I do not suppose you do. What loss would be entailed if they had to take this product back and rework it or even if it was destroyed, I do not know. But that is not the question that you are to pass on. It might, even if it did entail a loss to the Monticello Drug Company, and regardless of what that loss might be, still if they are as a matter of fact putting out a misbranded product, why you would not be concerned with whether they lost or whether they didn't. Your only question, that is what I am trying to say, your only question is whether the Monticello Drug Company is putting out an article, this new 666, whether they are putting out an article that is misbranded

and by that I mean misbranded or handled in the ways that I have mentioned here that would mislead members, average members of the buying public. If they are doing that, then you ought to find that and if they are doing it, then you ought to find against them.

"If, in your opinion, on the other hand, under all the evidence in this case the get-up, color, lettering, container and everything that you have heard about in this case would not be misleading to the average member of the public who buys 666, not misleading, why then, of course, there is no reason for stopping the Monticello Drug Company from putting it out in this form; and if you think that is true, you ought to find in favor of the Monticello Drug Company, which would mean that this product may be handled in the same way that it is being handled up to the time of filing this suit. That would mean that, in your opinion, under the evidence that there is no real danger or likelihood that members of the public would be mislead by it, and that if they bought it, they would know what they were getting and would not be mislead; and if that is what you think about it under this evidence you ought to find in favor of the Monticello Drug Company.

"So, that is your question. I state it finally that your only question is this: Is this new product under all the facts and circumstances that you have heard about in this case and under the definition which I have given you from the law, is this product a misbranded product? If it is, you ought to find in favor of the government. If it is not, you ought to find in favor of the Monticello Drug Company.

"Now, if you find in favor of the government, just write somewhere on the papers which you will have out, 'We the jury find—if you think it is a misbranded article—we the jury find in favor of the United States.' I believe that is the way the plaintiff is designated. On the other hand, if you think that this article is not misbranded in any of the ways which I have discussed with you and not misleading, then you ought to find in favor of the Monticello Drug Company, and the form of that verdict would be, 'We the jury find in favor of the Monticello Drug Company,' then date your verdict and let your foreman sign it."

"Mr. Davis. 'Your Honor please, in your recapitulation there, you probably inadvertently overlooked that if it was sold under the name of another drug, it was misbranded. It would not have to be misleading but if it is actually sold under the name of another drug, it would be misbranded.'

"The Court. 'Very well. I will see counsel in the office before the jury retires.'

[In the court's chambers]

"The Court. 'All right, any exceptions you want to get in the record?'

"Mr. Ashby. 'Doesn't the government proceed first?'

"The Court. 'Well, doesn't make any difference to me?'

"Mr. Walker. 'I think in the last two sub-divisions, under sub-section 'i' that if it is offered for sale under the name of another drug, then it doesn't have to be misleading.'

"The Court. 'It technically might not but the whole object of that part of the statute would be to keep from misleading anybody, I think.'

"Mr. Davis. 'Well, you may be right about that.'

"Mr. Ashby. 'Your Honor, the Intervenor takes exception to so much of the court's charge as submits to the jury any issue of whether the product here involved, the drug here involved, is in imitation of another drug; and likewise takes exception to such portion of the charge as submits to the jury the question of whether or not the drug here involved is offered for sale under the name of another drug. I have already argued that, Your Honor. I just make the point again.'

"The Court. 'All right.'

[Returning to the Court-room]

"Gentlemen of the jury, you may retire to the juryroom the Marshal will show you."

The jury, after deliberation, returned a verdict for the Government. On April 1, 1944, judgment was entered condemning the product and ordering that it be destroyed.

1232. Misbranding of "666." U. S. v. 119 Dozen Bottles of "666" (and 110 other seizure actions against "666"). Default decrees of condemnation and destruction. (F. D. C. Nos. 12425, 12427, 12451, 12452, 12454 to 12456, incl., 12469, 12471, 12472, 12479, 12484, 12488, 12490, 12504, 12510, 12745, 12761 to 12766, incl., 12817 to 12819, incl., 12893 to 12895, incl., 12897 to 12900, incl., 12904, 12905, 12940, 12954, 12957 to 12959, incl., 12990, 12991, 12995, 12997, 13000, 13005, 13006, 13037, 13038, 13041 to 13047, incl., 13093, 13190, 13194, 13317 to 13321, incl., 13326 to 13328, incl., 13335 to 13338, incl., 13340 to 13342, incl., 13356 to 13360, incl., 13362, 13363, 13391, 13402, 13569, 13605, 13616 to 13621, incl., 13629, 13630, 13791, 13792, 13805 to 13817, incl., 14016, 14017, 14057, 14071 to 14073, incl., 14340, 14341, 14368, 14407, 14437, 14438, 14846. Sample Nos. 28352–F, 28893–F, 28894–F, 34902–F to 34905–F, incl., 35059–F, 35067–F, 35070–F, 35071–F, 35073–F, 35892–F to 35895–F, incl., 35898–F to 35900–F, incl., 35980–F to 35984–F, incl., 53284–F to 53287–F, incl., 61375–F, 63292–F to 63295–F, incl., 63329–F, 63332–F, 63339–F, 63340–F, 63440–F, 63443–F to 63446–F, incl., 63482–F to 63485–F, incl., 63510–F, 63513–F to 63517–F, incl., 63549–F, 63725–F, 63726–F, 63732–F, 63734–F, 63735–F, 63737–F to 63739–F, incl., 63741–F to 63743–F, incl., 64003–F, 64004–F, 64011–F to 64014–F, incl., 64021–F, 64023–F to 64027–F, incl., 64030–F, 64031–F, 64033–F, 64035–F, 64041–F to 64044–F, incl., 64050–F, 64053–F, 64056–F to 64058–F, incl., 64060–F to 64062–F, incl., 64064–F to 64067–F, incl., 64069–F to 64071–F, incl., 66936–F to 66939–F, incl., 67670–F to 67672–F, incl., 67674–F to 67678–F, incl., 68220–F, 68221–F, 79619–F, 79620–F, 80338–F, 81352–F, 81353–F, 90121–F to 90123–F, incl., 90126–F to 90128–F, incl., 90137–F, 90138–F, 90144–F, 90214–F to 90216–F, incl., 90307–F, 90322–F, 90323–F, 90326–F, 90327–F, 90368–F, 90377–F to 90379–F, incl.)

Between May 25 and December 21, 1944, the United States attorneys for the Northern, Middle, and Southern Districts of Georgia, the Eastern, Middle, and Western Districts of Tennessee, the Eastern and Western Districts of South Carolina, the Eastern, Middle, and Western Districts of North Carolina, the Eastern District of Virginia, the Southern District of Ohio, the Western District of Missouri, the Western District of Kentucky, the Southern District of Texas, the Eastern and Western Districts of Arkansas, and the Eastern District of Illinois filed libels against a total of 5,260½ dozen bottles of "666," which was bottled in 3-ounce and 6-ounce containers and located at the following places: Quitman, Atlanta, Columbus, Macon, Athens, Savannah, Augusta, Albany, Americus, LaGrange, Newnan, Madison, Waycross, Dublin, Bowdon, and Waynesboro, Ga.; Chattanooga, Knoxville, Nashville, and Union City, Tenn.; Charleston, Union, Darlington, Camden, Saluda, Newberry, Laurens, Bennettsville, Chester, Woodruff, Anderson, Greenwood, and Sumter, S. C.; Gastonia, Charlotte, High Point, Winston-Salem, Wilmington, Fayetteville, Whiteville, Shelby, Lumberton, Clinton, Dunn, Raleigh, Durham, Wadesboro, Rockingham, Burlington, Leaksville, Madison, Sanford, Greensboro, Stoneville, and Thomasville, N. C.; Cincinnati, Ohio; Portsmouth, Suffolk, Newport News, and Norfolk, Va.; Kansas City and St. Joseph, Mo.; Paducah, Ky.; Galveston, Tex.; Pine Bluff, Little Rock, Russellville, Atkins, Ft. Smith, Morrilton, and Benton, Ark.; and Eldorado, Ill.

It was alleged in the libels that the article had been shipped between the approximate dates of August 8, 1942, and August 14, 1944, by the Monticello Drug Co., from Jacksonville, Fla., and New Orleans, La.

The composition of the article, its labeling, and the shape, color, and appearance of its containers were essentially the same as those of the product which was the subject of seizure in the cases reported in drug notices of judgment No. 1231.

The article was alleged to be misbranded because the labeling on the bottle and carton was misleading in that the numerals "666", appearing on the labeling in red on a yellow background, in combination with the yellow, red, and black color scheme of the other portions of the labeling, constituted a statement and device which created the impression and belief that the article was the product containing quinine sulfate which formerly for many years had been advertised, sold, and used as a treatment for malaria.

It was alleged to be misbranded further (1) because its container was so made, formed, and filled as to be misleading since the shape, color, and appearance of the container created the impression and belief that the article was the former product which contained quinine sulfate; (2) because it was an imitation of another drug in that its name, its labeling, its color, and the color, shape, and appearance of its container simulated the former product; and (3) because it was offered for sale under the name of another drug, the former product.

Between July 6, 1944, and February 3, 1945, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

1233. Misbranding of Von Tablets. U. S. v. 240,000 Von Tablets. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 9157. Sample No. 10623–F.)

On January 15, 1943, the United States attorney for the Northern District of California filed a libel against 240,000 tablets, each embossed with the letters "V O N," at San Francisco, Calif., alleging that the article had been shipped on or about December 9, 1942, from Minneapolis, Minn., and that it was in the possession of the San Francisco Von Co.; and charging that it was misbranded. On or about February 5, 1943, an amended libel was filed in clarification of the charges of misbranding.

The article was shipped in 20 drums, more or less, each of which was labeled in part: "12,000 Tablets * * * Manufactured for Geo. Von Neida, St. Paul, Minn.," After shipment, a portion of the article was repacked, on the premises of the San Francisco Von Co., into 100-tablet and 27-tablet size bottles bearing labels reading, in part: "Von's Pink Tablets."

It was also alleged in the libel that a number of booklets entitled, "Von's Pink Tablets Famous for Relief in Obstinate Cases of Gastritis and Ulcers Caused by Gastric Hyper-Acidity San Francisco Von Co. * * * San Francisco, California," were shipped on or about December 19, 1941, by the Riverside Press, Inc., from St. Paul, Minn.; and that the booklets were attached to the article and were distributed to purchasers of the article.

Examination of a sample indicated that each tablet of the article contained essentially 4.6 grains of bismuth subnitrate, 6.5 grains of magnesium oxide, and 5.4 grains of sodium bicarbonate.

The article was alleged to be misbranded in that the statements in the accompanying booklets which represented and suggested that the article, when used as directed, constituted an adequate treatment for gastritis and ulcers caused by gastric hyperacidity were false and misleading since the article did not constitute an adequate treatment for gastritis and ulcers from any cause.

On March 4, 1943, E. W. Downs, San Francisco, Calif., claimant, having filed exceptions to the libel on the ground that it did not state sufficient facts and that it was vague, uncertain, and ambiguous, an order was entered which overruled the exceptions. The claimant then consented to the entry of a decree of condemnation, and on August 23, 1943, judgment was entered condemning the product and ordering its release under bond for relabeling under the supervision of the Food and Drug Administration.

1234. Misbranding of Templeton's Raz-Mah Capsules. U. S. v. 68 Packages of Templeton's Raz-Mah Capsules. Default decree of condemnation and destruction. (F. D. C. No. 11526. Sample No. 49765–F.)

On December 29, 1943, the United States attorney for the Western District of Pennsylvania filed a libel against 68 packages of the above-named product at Erie, Pa., alleging that the article had been shipped on or about November 10, 1943, from Buffalo, N. Y., by Templeton's, Inc.; and charging that it was misbranded.

Examination of a sample of the article disclosed that it consisted essentially of aspirin, 4.12 grains per capsule, and caffeine, 0.69 grain per capsule, together with capsicum, charcoal, and extracts of plant drugs.

The article was alleged to be misbranded in that the statements in its labeling which represented and suggested that it was effective in the treatment or relief of symptoms of hay fever, bronchial irritations, and coughs due to colds or bronchial irritations, and that it was safe and effective in the relief of the symptoms of asthma, were false and misleading since the article was not so effective and was not safe and effective for use by many asthmatics. It was alleged to be further misbranded in that the statement of the active ingredients in the article was not prominently placed on the label with such conspicuousness (as compared with other words, statements, designs, or devices on the label) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, since it had been printed in small-size black type on a dark red background, and was practically illegible.

On January 26, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1235. Misbranding of Holford's Famous Inhalers. U. S. v. 663 Inhalers and 997 Circulars. Default decree of condemnation and destruction. (F. D. C. No. 11613. Sample No. 48272–F.)

On January 18, 1944, the United States attorney for the Northern District of Ohio filed a libel against 663 inhalers and 997 circulars at Cleveland, Ohio, alleging that the inhalers and the circulars had been shipped on or about October 7

and October 5, 1943, respectively, by Franklin A. Fink, trading as the Holford Co., Minneapolis, Minn.; and charging that the inhalers were misbranded.

Examination of the contents of an inhaler showed that it consisted of approximately 0.09 ounce of volatile oils such as mustard oil, eucalyptol, and camphor absorbed in a mixture of eucalyptus leaves, pine bark, lavender flowers, mustard seed, and other plant material.

The article was alleged to be misbranded (1) because of false and misleading statements appearing in the accompanying circulars entitled "Famous Inhaler," which represented and suggested that the inhaler was effective in the treatment of colds, catarrhal conditions, sinus irritations, sore throat, headaches, and the like; (2) in that the statements in the aforesaid circulars, "This famous Inhaler is produced by a compounding of pure chemicals—natural herbs and oils gathered from various parts of the globe. When thus combined, these herbs and oils produce a chemical action, when exposed to oxygen, that results in a soothing but potent and effective vapor. * * * For Years a Precious Secret Now Available to All For many years the secret of this marvelous formula was unknown only to one man. He assembled the ingredients and carefully compounded them himself, in the privacy of his home," were false and misleading since the herbs and oils contained in the inhaler did not produce a chemical action when exposed to oxygen, and the medicinal ingredients of the inhaler were not a secret, but were drugs which have been known and used generally for years; and (3) in that the common or usual name of each active ingredient was not prominently placed on the label of the inhaler with such conspicuousness and in such terms as to render it likely to be understood by the ordinary individual under customary conditions of purchase and use, since the statement, "Contains: Eucalyptus Leaves, Pine Bark, Lavender Flowers, Mustard Seed, Oils of Pine, Camphor, Eucalyptus, Mustard," did not differentiate between the active ingredients of the preparation and those substances which served merely as an absorbent of the oils and did not contribute to the effect of the inhaler.

On June 23, 1944, no claimant having appeared, judgment of condemnation was entered and the inhalers and circulars were ordered destroyed.

1236. Misbranding of Fairyfoot for Bunions. U. S. v. 25 Packages and 16 Packages of Fairyfoot for Bunions. Default decree of destruction. (F. D. C. No. 11652. Sample No. 40770–F.)

On January 19, 1944, the United States attorney for the District of Minnesota filed a libel against 25 $1.00-size packages and 16 49c-size packages of the above-named product at Minneapolis, Minn., alleging that the article had been shipped on or about August 6 and November 17, 1943, by the Fairyfoot Products Co., from Chicago, Ill.; and charging that it was misbranded.

Examination of a sample of the article disclosed that it consisted of adhesive plaster pads containing benzocaine and a small amount of an iron compound.

The article was alleged to be misbranded because of false and misleading statements in its labeling which represented and suggested that it was effective in stopping the pain and reducing the size of a bunion.

On March 2, 1944, no claimant having appeared, judgment was entered ordering that the product be destroyed.

1237. Misbranding of Jayne's Vermifuge. U. S. v. 71 Dozen Bottles of Jayne's Vermifuge. Default decree of condemnation and destruction. (F. D. C. No. 11701. Sample No. 47879–F.)

On January 24, 1944, the United States attorney for the Eastern District of Missouri filed a libel against 71 dozen bottles of the above-named product at St. Louis, Mo., alleging that the article had been shipped on or about December 18, 1943, by Dr. D. Jayne and Son, Inc., from Philadelphia, Pa.; and charging that it was misbranded.

Examination of a sample of the article disclosed that it consisted essentially of extracts of plant drugs, a small proportion of potassium carbonate, sugar, alcohol, and water, flavored with peppermint oil, and that it contained no rhubarb root. Tests made with the article upon both laboratory animals and humans showed that it was ineffective in removing large roundworms.

The article was alleged to be misbranded because of false and misleading statements and designs in its labeling which represented and suggested that the article was effective to remove large roundworms from children and adults.

On February 28, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1238. Misbranding of Armstrong's Drops. U. S. v. 84 Dozen Packages of Armstrong's Drops. Default decree of condemnation and destruction. (F. D. C. No. 11639. Sample No. 21991–F.)

On January 15, 1944, the United States attorney for the Western District of Pennsylvania filed a libel against 84 dozen packages of Armstrong's Drops at Pittsburgh, Pa., alleging that the article had been shipped on or about May 17 and October 27, 1943, from Los Angeles, Calif., by the F. E. Bucklin Co.; and charging that it was misbranded. The article was labeled in part: (Retail carton) "Armstrong's Drops Contents ¼ Fluid Oz. Manufactured for Armstrong Drop Co. * * * So. Pasadena, Cal."

The article was alleged to be misbranded in that the statement in its labeling, "¼ Fluid Oz.," was false and misleading as applied to the article, which was short weight; and in that the article failed to bear a label containing an accurate statement of the quantity of contents.

On February 25, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1239. Misbranding of Dr. Marshall's Scalp Medications. U. S. v. T. Noonan & Sons Co. Plea of guilty. Fine, $200. (F. D. C. No. 11353. Sample Nos. 56554–F to 56557–F, incl.)

On March 6, 1944, the United States attorney for the District of Massachusetts filed an information against T. Noonan & Sons Co., a corporation, Boston, Mass., alleging shipment of quantities of scalp lotions and creams on or about May 28 and July 30, 1943, from the State of Massachusetts into the State of New York. The articles were labeled in part: "Dr. Marshall's Scalp Medication [or "Medications"] Scalp Cream No. 1 [or "Scalp Cream No. 3," "Scalp Lotion A," or "Scalp Lotion B"]."

Analysis disclosed that the Scalp Cream No. 1 contained sulfur, salicylic acid, and tar oils incorporated in a base of petrolatum and lanolin; that the Scalp Cream No. 3 contained sulfur, Peru balsam, and betanaphthol incorporated in a petrolatum and lanolin base; that the Scalp Lotion A consisted essentially of betanaphthol, quinine, resorcinol, a saponifiable oil such as castor oil, alcohol, and water; and that the Scalp Lotion B consisted essentially of betanaphthol, resorcinol, alcohol, and water, perfumed with a small proportion of aromatic oils.

The articles were alleged to be misbranded because of the false and misleading statements appearing on their respective labels which represented and suggested that the Scalp Cream No. 1 would be efficacious in the treatment of oily dandruff or psoriasis; that the Scalp Cream No. 3 and the Scalp Lotion A would be efficacious in the treatment of falling hair or alopecia areata (bald spots); and that the Scalp Lotion B would be efficacious in the treatment of oily hair, oily dandruff, or psoriasis.

The Scalp Lotions A and B were [alleged to be misbranded] further in that they were not designated solely by a name recognized in an official compendium, and were fabricated from two or more ingredients, one of which was alcohol, and their labels did not bear the common or usual name of each active ingredient, including a statement of the quantity or proportion of alcohol present in the articles.

On March 14, 1944, a plea of guilty having been entered on behalf of the corporation, the court imposed a fine of $50 on each of 4 counts, a total fine of $200.

1240. Misbranding of Golden Key Antiseptic Medicated Cream. U. S. v. 117 Jars of Golden Key Antiseptic Medicated Cream. Default decree of condemnation and destruction. (F. D. C. No. 11221. Sample No. 52928–F.)

On December 2, 1943, the United States attorney for the District of Maryland filed a libel against 117 jars of the above-named product at Baltimore, Md., alleging that the article had been shipped on or about July 12, 1943, from Philadelphia, Pa., by the Windsor Chemical Laboratories; and charging that it was misbranded.

The article was alleged to be misbranded in that the statement on its label, "Net Wt. 10 Ozs.," was false and misleading since the jars contained less than 10 ounces net; and in that the product was in package form and its label failed to bear an accurate statement of the quantity of the contents.

On January 15, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1241. Misbranding of Vit-an-Min. U. S. v. S & R Laboratories, Inc. Plea of guilty. Fine, $200 and costs. (F. D. C. No. 10598. Sample Nos. 3064–F, 3065–F.)

On January 29, 1944, the United States attorney for the Northern District of Illinois filed an information against the S & R Laboratories, Inc., Chicago, Ill.,

alleging shipment of a quantity of the above-named product, on or about April 20, 1943, from the State of Illinois into the State of Missouri.

Analysis disclosed that the article consisted of a light brown, powdered material containing, essentially, vitamins A, D, B_1, and riboflavin, and the minerals calcium, phosphorus, and iron.

The article was alleged to be misbranded because of false and misleading statements appearing in its labeling which represented and created the impression that the article would give the user health and beauty; that it would insure normal functioning and correct abnormalities of the brain, pituitary gland, thyroid glands, parathyroid glands, thymus gland, spleen, pancreas, adrenal glands, gonads, prostate gland, pineal gland, mammary glands, and spinal cord; that it would be efficacious in the cure, mitigation, treatment, or prevention of diseases of the eyes, nasal sinuses, tongue, throat and bronchial tubes, lungs, heart, liver and gall bladder, stomach and digestive system, kidneys, bladder, nerves, blood and blood vessels, muscles, bones and joints, ears, hair, nails, skin, teeth, gums, and ovaries; that it would be efficacious in the cure, mitigation, treatment, or prevention of neurasthenia, headache, diabetes, kidney stones and infections, bladder stones and infections, anemia, uterine headache, acidosis, acne, eczema, pimples, underweight, arthritis, gout, rheumatism, asthma, auto-intoxication, high blood pressure, boils, Bright's disease, bronchitis, colds, catarrh, colitis, hyperacidity, ulcer of the digestive organs, gastric and duodenal enteritis, gastritis, failing eyesight, cataract, falling hair, gall stones, goiter, hardening of the arteries, hay fever, leucorrhea, low vitality, lack of pep, nervousness, sciatic rheumatism, neuralgia, neuritis, nerve exhaustion, obesity, poor circulation, sex indifference, tooth decay, bleeding gums, tuberculosis of the lungs, night blindness, tear duct infection, corneal ulcers, dyspepsia, retarded growth, brain disorders, heart diseases, weakened blood capillaries, tendency to bleeding, low blood pressure, irregular heart action, peptic ulcer, bone abscesses, bowed legs, and diarrhea; and that it would extend youth, prolong life, promote growth and appetite, protect against infection, protect from scurvy, prevent pellagra, and overcome sterility.

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

On April 24, 1944, the defendant filed a motion to quash the information on the grounds (1) that the article was not a drug; and (2) that each of the counts of the information, when considered with the affidavits attached thereto, were confusing, and without sufficient certainty and particularity. Argument by counsel on the motion was thereafter heard, and on May 19, 1944, an order by the court in denial of the motion was entered. On June 26, 1944, a plea of guilty having been entered on behalf of the defendant, the court imposed a fine of $200 and costs.

1242. Misbranding of Beawun Vitamin B_1 Tablets. U. S. v. 708 Envelopes of Beawun Vitamin B_1 Tablets. Default decree of condemnation and destruction. (F. D. C. No. 11218. Sample No. 42584–F.)

On December 9, 1943, the United States attorney for the Western District of Washington filed a libel against 708 envelopes, each containing 25 tablets, of the above-named article, alleging that it had been shipped on or about May 18, 1943, from Chicago, Ill., by the American Nutrition Co.; and charging that it was misbranded.

Examination of a sample disclosed that the article contained approximately one milligram of vitamin B_1 per tablet.

The article was alleged to be misbranded in that the statement in the labeling which represented and suggested that it would be efficacious to prevent and correct fatigue, flabby digestive muscles, constipation, neuritis, beriberi, polyneuritis, flatulence, dyspepsia, headaches, lack of stamina, "run down" feeling, delirium tremens, poor appetite, and subnormal growth; and that nutrition surveys show that the average child and adult in the United States does not receive enough thiamine for the highest state of health, were false and misleading since use of the article would not be of value in preventing or correcting the various symptoms, conditions, and diseases named and suggested, and since nutrition surveys do not show that the average child and adult receives inadequate amounts of vitamin B_1.

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

On January 6, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1243. Misbranding of Class' Vitamin, Mineral and Herb Formula. U. S. v. 10¾ Cases of Class' Vitamin, Mineral and Herb Formula. Default decree of condemnation and destruction. (F. D. C. No. 11065. Sample Nos. 53443–F, 53470–F.)

On November 8, 1943, the United States attorney for the Southern District of West Virginia filed a libel against 10¾ cases, each full case containing 24 8-ounce bottles, of the above-named product at Charleston, W. Va.; and on November 30, 1943, an amended libel was filed to cover the seizure of an additional lot of 24 cases of the product at Charleston. It was alleged that the article had been shipped on or about August 19 and 25, 1943, from Dayton, Ohio, by the Granville Class Laboratories; and charged that the article was misbranded.

Examination disclosed that the article was a mixture of water, glycerin, and alcohol containing caffeine, phosphate compounds, plant extractives, and a trace of saccharin.

It was alleged to be misbranded in that the name of the article and certain statements appearing in its labeling which represented and implied that the article was of value by reason of its vitamin and mineral content; and that it was of value in correcting poor health, nervousness, irritability, and poor appetite by reason of the fact that it contained vitamins, minerals, and herbs, were false and misleading since the article was not a significant source of vitamins (with the exception of vitamin B_1) and minerals, and it was not of value in correcting the conditions named, nor would its use result in correcting poor health.

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

On February 18, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1244. Misbranding of Hi-Lo Tablets. U. S. v. 34 Bottles of Hi-Lo Tablets. Default decree of condemnation and destruction. (F. D. C. No. 10051. Sample No. 38130–F.)

On June 14, 1943, the United States attorney for the Eastern District of Wisconsin filed a libel against 34 bottles, each containing 540 tablets, of the above-named product at Milwaukee, Wis., alleging that the article had been shipped on or about April 20, 1943, from St. Louis, Mo., by the Hi-Lo Products Co.; and charging that it was misbranded.

The article was labeled in part: "Each Tablet Contains Calcium Pantothenate * * * 4.4 Milligrams Vitamin B_1 * * * 111 U. S. P. Units Vitamin B_2 * * * 666 Micrograms Vitamin B_6 * * * 111 Micrograms Vitamin P–P (Niacin) * * * 3333 Micrograms."

A microanalytical examination showed that the article was essentially dried, powdered yeast.

The article was alleged to be misbranded because of false and misleading statements appearing on the carton and bottle labels and in accompanying circulars entitled, "Now Hi-Lo Products presents Hi-Lo Anti-Gray Hair Vitamin Tablets Vitamin B Complex Plus," "Hi-Lo Anti-Gray Hair Tablets," "Gray Hair? Have you heard what Vitamins are doing to Restore Color to Gray Hair and to Prevent Hair from Turning Gray?," and "Before You Buy Vitamins Look at the Labels," which represented and suggested that the article, when taken as directed, was effective in restoring the natural color to gray hair, in preventing the occurence of gray hair, in improving health, and in correcting or preventing nervousness, faulty elimination, headache, dizziness, fatigue, rapid heartbeat, and numbness of feet and ankles.

It was also alleged in the libel that a number of copies of each of the circulars accompanied the article when it was introduced into and while it was in interstate commerce, in the following manner: That a copy of the circular entitled "Hi-Lo Anti-Gray Hair Tablets" was enclosed in each carton containing the tablets at the time of shipment; that a number of copies of the other circulars were received by the consignee at its establishment in Milwaukee, Wis., from the Hi-Lo Products Co., St. Louis, Mo., on or about March 25, 1943, which was prior to the shipment of the article; that certain of the circulars were thereafter prominently displayed in the consignee's establishment, together with, in association with, and in close proximity to the article; and that copies of some of the circulars were distributed to purchasers of the article.

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

On March 13, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1245. Misbranding of Bio-Mineral. U. S. v. George Aristotle and Michel N. Manteris (Bio-Mineral Products Co.). Pleas of guilty. George Aristotle fined $750 and placed on probation for 2 years; Michel Manteris fined $250 and placed on probation for 1 year. (F. D. C. No. 10569. Sample No. 3044–F.)

On November 22, 1943, the United States attorney for the Eastern District of Michigan filed an information against George Aristotle and Michel N. Manteris, trading as the Bio-Mineral Products Co., Detroit, Mich., alleging shipment on or about December 21, 1942, from the State of Michigan into the State of Missouri of a quantity of Bio-Mineral which was misbranded.

Analysis of the article disclosed that it consisted essentially of a water solution containing per U. S. gallon: Iron sulfate, 3,546.0 grains; magnesium sulfate .7$H_2$0, 458.6 grains; calcium sulfate, 52.0 grains; phosphate as sodium phosphate, 26.9 grains; and a minute amount of aluminum sulfate.

The article was alleged to be misbranded (1) because of false and misleading statements, together with designs illustrating a healthy colon and an abnormal colon, borne on a poster accompanying the article, which represented and suggested that the article would be efficacious in the cure, mitigation, treatment, or prevention of rheumatism, constipation, weak kidneys, ailments of the colon leading to serious complications, piles, colitis, and appendicitis; that it would keep the colon clean and healthy by eliminating accumulated poisonous matter; that it was recommended by the medical profession generally; and that it was a solution of life-giving minerals; (2) in that the name "Bio-Mineral" was misleading since it created the impression that the article, when taken as directed, would supply the mineral elements necessary to life, whereas, when taken as directed, the article would not supply the mineral elements necessary to life; (3) in that the statement, "A natural mineral aid to be taken as a supplement for mineral deficiency," borne on the label, was false and misleading since the statement represented and suggested that the article, when used in accordance with the directions, "Half teaspoonful, or less * * * before breakfast and before retiring," would supply the user with sufficient amounts of the essential minerals to be of value in the treatment of conditions resulting from mineral deficiency, whereas the article contained, with the exception of iron, insignificant and inconsequential amounts of minerals; and (4) in that its labeling was misleading since it failed to reveal the fact that, with the exception of ferric sulfate, the article contained insignificant and inconsequential amounts of the ingredients declared in the labeling, which fact was material in the light of the following statement on the label: "Contains approximately—in gr. per. U. S. gallon: Free (uncombined Sulphuric Acid 879. Ferric Sulphate (Fe 2(SO4)3) 3834. Aluminum Sulphate (Al 2(SO4) 3) 59. Calcium Sulphate (Ca SO4) 177. Magnesium Sulphate (Mg SO4 7H2O) 800. Phosphoric Acid (as Sodium Phosphates) 145. (Na 2HPO4) Water 52517—Total 58411 Gr."

It was also alleged in the information that, after the shipment of the article, the defendants offered to supply the consignee with certain literature; that, in response to an order from the consignee, the defendants shipped, on or about January 18, 1943, a number of envelopes, each containing a circular entitled "Important Message"; that thereafter, and while the article was held for sale by the consignee, the defendants, by means of the consignee and its employees, caused a number of the envelopes and circulars to be placed with and to accompany the article; and that these acts of the defendants resulted in the article being misbranded by reason of certain false and misleading statements in the circulars and envelopes, together with designs showing a healthy colon and, by contrast, various abnormal conditions of the colon. These statements and designs represented and suggested that the article would be efficacious in the cure, mitigation, treatment, or prevention of constipation, acid indigestion, bloating, sourness, bad breath, indisposition, common headaches, frequent colds, common stomach disorders, a tired feeling, weak kidneys and getting up nights, decaying teeth, weak eyes, nervousness, a tired, lazy feeling, poor vision, lumbago, and acid in the stomach; that the article would restore ruined, weak, sick human bodies; that it would give the user pep, good appetite, rosy color, and zeal to work; that it would add years to one's life; that it would be efficacious in the treatment of rheumatism, infantile paralysis, gall stones, and stomach and kidney ailments; that it would be efficacious to rid the colon of waste that had been collecting, probably for years, like rust in an iron pipe; that it would bring about better health, cause the bowels to become regular, cause black, hard waste to break from the walls of the colon, produce three normal eliminations daily, like a healthy child, and cause the user to become free of the effects of constipation, gas toxins, etc.; that it would cause small pieces of white stone, threads, and crystal-like

matter to pass in the urine; that it would enable one to eat any food desired; that it would improve digestion; that it was an appropriate treatment in general for mineral deficiency diseases and for weak back, paleness, circles under the eyes, bladder trouble, arthritis, neuritis, sciatica, leg pains, and stiff or swollen joints; that it was a drugless road to health; that it would be efficacious in the prevention of weak, run-down organisms which prepare the ground for tuberculosis, cancer, nephritis, heart disease, appendicitis, piles, asthma, goiter, and rheumatism; that it would produce the benefits ordinarily ascribed to and associated with consumption of the waters of mineral springs; that it possessed rejuvenating properties; that it would give one a healthy color; and that it would be efficacious in the prevention of goiter.

On May 8, 1944, the defendants entered pleas of gulity, and on September 7, 1944, the defendant Aristotle was fined $750 and committed for 1 year, and the defendant Manteris was fined $250 and committed for 6 months. The prison sentences were suspended, and Aristotle was placed on probation for 2 years and Manteris for 1 year.

1246. Adulteration and misbranding of Sea-Soi, and misbranding of various other drugs. U. S. v. 91 Bottles of West's Imported Sea Vegetable Tablets, etc. Consent decree of condemnation. Products ordered released under bond for relabeling. (F. D. C. Nos. 9608, 9900. Sample Nos. 13926–F to 13935–F, incl., 14804–F, 14811–F to 14816–F, incl., 14820–F to 14827–F, incl.)

On March 29 and May 12, 1943, the United States attorney for the Southern District of California filed libels against the following products, located at Los Angeles, Calif., and packed in bottles of various sizes: 130 bottles of West's Imported Sea Vegetable Tablets; 223 bottles of Sea Vegecene (Powder); 226 bottles of Ocean Lax Tablets; 140 bottles of Sodeom Tablets; 63 bottles of Sea-V-Aid Tablets; 118 bottles of Sea-Vo-Kra tablets; 116 bottles of Imported Sea Vegetables Vitaminized with added Vitamin 'A,' in tablet form; 99 bottles of FYA Tablets; 201 bottles of D–X Tablets; 16 bottles of Sea-Soi; and 78 bottles of Kalseom Tablets. It was alleged in the libels that the articles had been shipped between the approximate dates of February 17, 1942, and January 23, 1943, by Mineralized Foods, Inc., Baltimore, Md.

Examination of West's Imported Sea Vegetable Tablets disclosed that they contained seaweed; and that they yielded approximately 29.5 percent inorganic constituents, including, per tablet, 1.2 milligrams of iodine, 43 milligrams of calcium, 6 milligrams of magnesium, 17 milligrams of phosphorus, and 0.3 milligram of iron. The article was alleged to be misbranded because of false and misleading statements on the bottle label and in a circular entitled, "West's Imported Sea Vegetables," which represented, suggested, and implied that there exists in the ordinary foods consumed a substantial deficiency in the mineral elements supplied by the article, which deficiency would result in the various disease conditions named and suggested in the labeling, i. e., arteriosclerosis, apoplexy, high blood pressure, premature aging, intestinal catarrh or inflammation, constipation, some forms of eye trouble, skin eruptions, sensitive nerves, irritability, bad temper, a listless, tired feeling, kidney diseases, rheumatism, arthritis, neuritis, tardy glandular functioning, slow child growth, goiter, thyroid disturbances, dry skin and falling hair, anemia, faulty metabolism, poor teeth, delayed coagulation of blood, rickets, weak bones, stiff joints, hardening of the arteries, acidosis, faulty elimination, and diuresis; that use of the article would prevent or correct those disease conditions; and that the article was of nutritional and therapeutic value because of the presence of sodium, potassium, and magnesium.

Examination of the Sea Vegecene (Powder) disclosed that it consisted essentially of a mixture of dried and powdered seaweed, containing, in each level teaspoonful (2.35 grams), approximately 3 milligrams of iodine, 1.5 milligrams of iron, and 4.0 milligrams of phosphorus. It was alleged to be misbranded because of false and misleading statements on its label which represented and suggested that the article was of nutritional significance because of the presence of iron, sodium, and phosphorus, as well as other unnamed minerals.

Examination of the Ocean-Lax disclosed that it consisted essentially of dried plant material including rhubarb and seaweed; and that it yielded, per tablet, approximately 0.3 milligram of iodine. It was alleged to be misbranded because of false and misleading statements on the jar label and in a circular entitled, "Are You Occasionally Constipated?", which represented, suggested, and implied that the article was appropriate for food purposes; that its laxative ingredients were derived from the ocean; that the alkalinity and amount of minerals supplied by the article were consequential; and that the use of the article as directed would be effective in the prevention of simple goiter, arteriosclerosis, apoplexy, and high

blood pressure; that it would cleanse the alimentary canal of poisonous wastes; that it would alkalize the digestive tract, supply iodine to the system, stimulate intestinal activity, retard premature aging, and increase the intake of essential food minerals. It was alleged to be misbranded further (1) in that the label failed to reveal the material fact that the sea plants and peppermint leaves in the article did not contribute to its laxative effects; and (2) in that the label did not show that the only active ingredients in the preparation were senna pods, purging cassia, and rhubarb root.

Examination of the Sodeom disclosed that it contained dried and powdered seaweed, calcium phosphate with small amounts of calcium carbonate, and starch; and that it yielded approximately 39.6 percent inorganic constituents, including, per tablet, 0.7 milligram of iodine. The article was alleged to be misbranded because of false and misleading statements on the jar label and in a circular entitled, "Introducing 'Sodeom' from the Ocean," which represented, suggested, and implied that the article was of nutritional significance because of the presence of sodium; and that it was of value in treating and preventing arthritis, neuritis, rheumatism, acidosis, and other nutritional deficiency conditions, throbbing, aching pain in the hands, shoulders, legs, and back, nervous, sleepless nights, kidney stones, rheumatic fever, and premature aging.

Examination of the Sea-V-Aid disclosed that it contained vegetable tissue, including seaweed, and yeast; and that it yielded approximately 26 percent inorganic constituents, including 0.6 milligram of iodine per tablet. It was alleged to be misbranded because of false and misleading statements on the bottle label and in a circular entitled, "Are You A Victim of Nerves?," which represented, suggested, and implied that the article was of nutritional value because of the presence of minerals; that it would prevent or correct jumpy, snappy nerves, nervous condition due to dietary deficiency, premature aging, arteriosclerosis, apoplexy, high blood pressure, and pellagra; and that the principal ingredients of the article were derived from the sea.

Examination of the Sea-Vo-Kra disclosed that it contained dried, powdered okra and dried seaweed; and that it yielded approximately 27.1 percent inorganic constituents, including 0.7 milligram of iodine per tablet. It was alleged to be misbranded in that the statements on the jar label and in a circular entitled, "Even Though You Have Ulcers of the Stomach or Intestines," which represented, suggested, and implied that the article was of value in the prevention or treatment of ulcers, and that it was of nutritional value as a source of food minerals and vitamins A, B, C, and D, were false and misleading since the article was not of value in the prevention or treatment of ulcers, was not of value as a source of food minerals, with the exception of the extent to which it may have provided a supplementary source of iodine, and was not a consequential source of vitamins A, B, C, and D.

Examination of the Imported Sea Vegetables Vitaminized with added Vitamin 'A' disclosed that the article contained dried seaweed; and that it yielded 43 percent inorganic constituents, including 0.6 milligram of iodine per tablet. It was alleged to be misbranded because of false and misleading statements on the jar label and in a circular entitled, "Watch Out! Beware of Night Blindness!," which represented, suggested, and implied that there exists in the ordinary foods consumed a substantial deficiency in the mineral and vitamin elements supplied by the article, which deficiency would result in the various disease conditions named and suggested, i. e., sinus conditions, colds, mucus and catarrhal infections, night blindness, poor vision, arthritis, premature aging, arteriosclerosis, apoplexy and high blood pressure; and that use of the article would prevent or correct those disease conditions.

Examination of the F Y A Tablets disclosed that they contained dried seaweed, small quantities of calcium carbonate, starch, powdered cinnamon, sucrose, and coloring; and that they yeilded approximately 43.7 percent inorganic constituents, including 0.6 milligram of iodine per tablet. The article was alleged to be misbranded because of false and misleading statements on the jar label and in a circular entitled, "Invitation to the Waltz * F Y A For Men and Women past 40," which represented, suggested, and implied that there exists in the ordinary foods consumed a substantial deficiency in the mineral elements supplied by the article, which deficiency would result in premature aging, weakness of the glandular system, arteriosclerosis, apoplexy, high blood pressure, and physical slowdown; and that use of the article would prevent or correct those disease conditions.

Examination of the D–X Tablets disclosed that they contained seaweed and other plant material; and that they yielded approximately 23.7 percent inorganic

constituents. The article was alleged to be misbranded in that the statements on the bottle label and in a circular entitled "Diabetes?," which represented, suggested, and implied that inadequacies in the mineral content of foods ordinarily consumed are responsible for the development of diabetes, and that use of the article would prevent or cure this disease, were false and misleading since diabetes is not a deficiency disease resulting from inadequacies in mineral intake, and consumption of the article would not effect the results stated or implied in the labeling.

Examination of the Sea-Soi disclosed that it contained soy beans, dried seaweed, and sugar, and that it yielded approximately 3.6 percent of inorganic constituents containing, per 2 ounces, 170 milligrams of phosphorus, 3.5 milligrams of iron, and 5 milligrams of iodine. It was alleged to be adulterated in that its strength differed from that which it was represented to possess, "18 milligrams food iron—more than the full minimum daily adult requirement," per 2 ounces. The article was alleged to be misbranded because of false and misleading statements on the bottle label and in a circular entitled, "Nervous . . . Anemic? Sea-Soi?," which represented, suggested, and implied that use of the article in accordance with the directions for use would prevent or correct shortness of breath, rapid heart palpitation, flabby flesh, pale skin, a tired feeling, excessive weight, irritability and supersensitivity, disturbance in the stomach, gastric secretions, lack of aggressiveness and ambition, chlorosis in adolescent girls, lassitude, capricious appetite, indigestion and constipation, a general run-down condition, underweight, iron deficiency, sinus conditions, colds, mucus and catarrhal conditions, rheumatoid arthritis, beriberi, loss of appetite, general debility, premature graying, scurvy, anemia, pyorrhea, rheumatoid fever, rickets, bone deficiencies, calcium deficiency, metabolism, arteriosclerosis, apoplexy, and high blood pressure; and that the pincipal ingredients of the article were derived from the sea and soy beans.

The article known as Kalseom Tablets was labeled in part: "Kalseom * * * Consists of Imported variety of Sea Vegetables * * * carefully blended with Bone Calcium Phosphate fortified with Vitamin 'C' (Ascorbic Acid) and Vitamin D (Ergosterol)." The article was alleged to be misbranded because of false and misleading statements on the bottle label and in a circular entitled "Can This Be True?," which represented, suggested, and implied that there exists in the ordinary foods consumed a substantial deficiency in the mineral elements supplied by the article, which deficiency would result in tuberculosis, asthma, hay fever, allergy, headaches, skin eruptions, gastric, muscular, and nervous disturbances, weak pulse, poor digestion, poor teeth, and brittle fingernails; and that use of the article would prevent or correct those conditions.

Misbranding of all of the articles and adulteration of the Ocean-Lax and Sea-Soi were also alleged under the provisions of the law applicable to foods, as reported in the notices of judgment on foods.

On August 10, 1943, Mineralized Foods, Inc., claimant, was granted its motion for the removal of the libel proceedings to a district of reasonable proximity to the city of Baltimore, Md. On October 7, 1943, the cases having been transferred to the District of Columbia, an order having been entered for their consolidation, and the claimant having consented to the entry of a decree, judgment of condemnation was entered and the products were ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

1247. Misbranding of Nuxated Iron. U. S. v. 21⅓ Dozen Packages of Nuxated Iron. Default decree of condemnation and destruction. (F. D. C. No. 11978. Sample No. 76274–F.)

On March 11, 1944, the United States attorney for the Northern District of New York filed a libel against 21⅓ dozen packages of Nuxated Iron at Binghamton, N. Y., alleging that the article had been shipped on or about January 17, 1944, from Stamford, Conn., by Dae Health Laboratories, Inc.; and charging that it was misbranded.

Examination disclosed that the article consisted essentially of ferrous sulfate (64 milligrams per tablet), strychnine, compounds of calcium, magnesium and sodium, including carbonates and glycerophosphates, together with aromatic principles.

The article was alleged to be misbranded because of false and misleading statements in its labeling which represented and suggested that it would be an adequate treatment for run-down conditions and iron deficiency.

On June 21, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS FOR VETERINARY USE

1248. Misbranding of medicated charcoal. U. S. v. Des Moines Incubator Co. Plea of guilty. Fine, $200 and costs. (F. D. C. No. 11342. Sample No. 3168–F.)

On February 2, 1944, the United States attorney for the Southern District of Iowa filed an information against the Des Moines Incubator Co., a corporation, Des Moines, Iowa, alleging shipment of a quantity of medicated charcoal on or about March 5, 1943, from the State of Iowa into the State of Nebraska.

Analysis disclosed that the article consisted essentially of charcoal impregnated with mineral salts, including small proportions of silica, calcium carbonate, and magnesium sulfate.

The article was alleged to be misbranded (1) in that the statements in its labeling which represented and suggested that the article contained menthol, methyl salicylate, and thymol, and that it contained Glauber's salt and Epsom salt in amounts sufficient to be of therapeutic importance, were false and misleading since the article did not contain menthol, methyl salicylate, or thymol, and it did not contain Glauber's salt or Epsom salt in amounts sufficient to be of therapeutic importance, but contained only insignificant amounts of Glauber's salt and Epsom salt; (2) in that the statements in its labeling, "To prevent and correct White Diarrhoea and all other forms of digestive disturbances in Chicks and Fowls * * * Guaranteed under the Food and Drugs Act June 30th 1906. Serial 13014," were false and misleading since the article would not be efficacious to prevent or correct white diarrhea or all other forms of digestive disturbances in chicks or fowls, and it had not been approved by the United States Government, and did not comply with all Federal laws relating to drugs; (3) in that the statement in its labeling, "Net Weight 5 Lbs.," was false and misleading since the cartons containing the article contained a smaller amount; and (4) in that it was in package form and its label did not bear an accurate statement of the quantity of the contents. It was alleged to be misbranded further because of false and misleading statements appearing in its labeling which represented and suggested that the article would be efficacious in the cure, mitigation, treatment, or prevention of intestinal disturbances in chicks and fowls, and cholera, white diarrhea, or other forms of intestinal complaints in chicks or fowls; that it would be efficacious to keep chicks in the best of condition and to bring relief in intestinal or bowel complaints in 24 hours; and that it would insure healthy chicks, growing stock, and matured fowls.

On May 13, 1944, a plea of guilty was entered on behalf of the defendant, and the court imposed a fine of $200 and costs.

1249. Misbranding of Es-A-Deen. U. S. v. Hugo Heinrich Julius Schaefer (American Research Laboratories and Schaefer Biological Laboratories). Plea of nolo contendere. Fine, $200. (F. D. C. No. 10610. Sample Nos. 5878–F, 6090–F.)

On December 10, 1943, the United States attorney for the Eastern District of Missouri filed an information against Hugo Heinrich Julius Schaefer, an individual trading as the American Research Laboratories and as the Schaefer Biological Laboratories, St. Louis, Mo., alleging shipment, from on or about December 13, 1942, to January 24, 1943, from the State of Missouri into the States of Tennessee and Illinois of quantities of Es-A-Deen.

Analysis disclosed that the article consisted essentially of water, small proportions of sod um sulfocarbolate, zinc sulfocarbolate, calcium sulfocarbolate, and acriflavine hydrochloride, and that it contained no bismuth carbolate or arecaline hydrobromide.

The article was alleged to be misbranded because of false and misleading statements appearing in its labeling which represented and suggested that it would be efficacious in the cure, mitigation, treatment, or prevention of colic, coccidiosis, black head, white diarrhea, and roundworms in poultry; that it would be an efficacious treatment for droopy chicks; and that, when inserted twice daily with a syringe into the crops of poultry that could not eat or drink, it would be efficacious in the cure, mitigation, and treatment of droopy chicks and the other abovementioned conditions. It was alleged to be further misbranded in that the statements "Areocoline Hydrobromide 0.7%, Bismuth Carbolate 2.0%," appearing on its labels, were false and misleading since the article contained no arecaline hydrobromide or bismuth carbolate.

On April 3, 1944, a motion to strike was submitted to the court by the defendant and, after argument by counsel, the court, on April 4, 1944, overruled the motion, handing down the following opinion:

HULEN, *District Judge:* "Defendant files his motion to strike the affidavit attached to the information filed in this case. The Information, charging misdemeanor, was filed by the District Attorney by leave of Court. The Information is signed by the District Attorney. Attached to the Information is an affidavit of one Henry E. Moskey, a veterinarian connected with the Food & Drug Administration of the United States Government. The Information in two counts charges misbranding of a medicine represented as a preventive of certain poultry diseases. The affidavit purports to state facts showing probable cause. Defendant's Motion to Strike the Affidavit from the Information and from the files in this cause alleges grounds therefor:

"(1) That the affidavit constitutes hearsay evidence and is not legally part of the information:

"(2) That the affidavit could be read to the jury and thereby deprive defendant of his right to cross-examine affiant:

"(3) That the affidavit is hearsay:

"(4) That the affidavit is self-serving:

"(5) That the affidavit is unwarranted in law and is prejudicial.

"It would appear from defendant's motion that he has misconstrued the purpose served by the affidavit attached to the Information. See Dinger v. United States, 28 F. (2d) 548 (8th Circuit).

"We make the observation that in our judgment the affidavit is no part of the Information; is not evidence hearsay or otherwise; should not be read to the jury in a trial of the cause, and therefore, without holding that the affidavit is improperly filed, we do find that the affidavit cannot prejudice the defendant in any of the particulars set forth in Motion to Strike.

"Defendant's Motion to Strike is overruled."

On June 5, 1944, the defendant entered a plea of nolo contendere and the court imposed a fine of $100 on each count, a total fine of $200.

1250. Misbranding of veterinary products. U. S. v. 276 Bags of Economy Stock Powder, 85 Bags of Economy Mineral Compound, 8 Bags of Economy Horse Powders, 1 Bag of Economy Drenching Powder, and various quantities of printed matter. Consent decree of condemnation. Products ordered released under bond; printed matter ordered destroyed. (F. D. C. No. 10180. Sample Nos. 37973–F to 37975–F, incl., 37977–F.)

On July 12, 1943, the United States attorney for the Northern District of Indiana filed a libel against the following articles and printed matter at Fort Wayne, Ind.: 276 50-pound bags of Economy Stock Powder, 85 100-pound bags of Economy Mineral Compound, 8 25-pound bags of Economy Horse Powders, 1 25-pound bag of Economy Drenching Powder, 3,000 booklets entitled "The Key to Success Economy Stock Powder," 450 circulars entitled "Directions for Feeding Economy Stock Powders," 300 circulars entitled "Economy Mineral Compound," 100 circulars entitled "Economy Horse Powder," and 50 leaflets entitled "Directions for Using Economy Drenching Powder." It was alleged that the articles had been shipped from Shenandoah, Iowa, by the Economy Hog & Cattle Powder Co., on or about March 3, 1942, and January 4, 1943. The Stock Powder was labeled in part: "Manufactured by James J. Doty, Ltd. Shenandoah, Iowa"; and the other articles were labeled in part: "Manufactured by the Economy Hog & Cattle Powder Co. Shenandoah, Iowa."

Analysis disclosed that the Stock Powder consisted essentially of sodium sulfate, calcium carbonate, sodium bicarbonate, sulfur, charcoal, small amounts of iron oxide, manganese sulfate, sodium thiosulfate, plant drugs including American wormseed, and not more than 0.004 percent of iodine; that the Mineral Compound consisted essentially of calcium carbonate, sodium sulfate, small amounts of sodium bicarbonate, charcoal, sulfur, iron oxide and manganese sulfate with traces of an iodide, a phosphate, anise, and molasses, and contained not more than 0.4 percent of phosphorus and not more than 0.009 percent of iodine; that the Horse Powders consisted essentially of sodium sulfate, sodium bicarbonate, sodium carbonate, sulfur (3.3 percent), charcoal (3.7 percent), small amounts of manganese sulfate, sodium thiosulfate, potassium iodide, and plant drugs including American wormseed, and contained not more than 0.006 percent of iodine; and that the Drenching Powder consisted essentially of sodium sulfate, sodium bicarbonate, charcoal, sulfur, calcium carbonate, and a laxative plant drug.

The articles were alleged to be misbranded because of false and misleading statements in their labeling, i. e., in the aforesaid printed matter, which represented, suggested, and created the impression, (1) in the case of the Stock Powder, that it would be efficacious in the treatment of worms, thumps, lung trouble, cough, white scours in pigs, necro, gastritis, enteritis, spasmodic colic, and bad stomach; that it was a laxative; that it was a regulator and corrective for all

livestock; that it would restore the healthy functions of the body, act as a cleanser and filter, aid digestion, be valuable in cases of toxic poison conditions, prevent gland troubles, lumbricoid worms, lung worms, thorn-headed worms, whipworms, kidney worms, and constipation; and that it was of value in the care of unthrifty, out-of-condition hogs; (2) in the case of the Mineral Compound, that it would be efficacious to make cattle go on feed quicker, be less apt to stick, and be more free from sour stomach; that by its use there would be less belching of feed; and that it would promote more uniform growth and better health and vitality, and aid greatly in bringing heifer calves into production more quickly; (3) in the case of the Horse Powders, that the article was a standard conditioner, regulator, and worm expellor; and that it would be efficacious in the treatment of horse bots, general run-down condition, colic, distemper, bloating, impaction, smut poisoning, and sleeping sickness in horses (infectious encephalomyelitis); and (4) in the case of the Drenching Powder, that it would be efficacious in the treatment of impaction, bloating, badly deranged stomach, dyspeptic troubles, garget or other forms of udder troubles, colic, founder, and distemper; and that it would give quick relief for an animal suffering from bloat, impaction, digestive disorders, badly deranged stomach, or retained afterbirth.

It was also alleged in the libel that the Economy Hog & Cattle Powder Co. shipped the drugs via its own trucks; that the booklets, circulars, and leaflets were shipped by the James J. Doty Co., Ltd., via its own trucks from Shenandoah, Iowa; that the drugs and printed matter were received in interstate commerce by the branch manager for both companies at their common place of business in Fort Wayne, Ind.; that the printed matter was there brought together with the drugs to which they referred, for distribution to purchasers of the articles; and that the receipt of the drugs and the booklets, circulars, and leaflets relating thereto, after shipment to a common destination for joint distribution to purchasers, constituted a transaction in interstate commerce; and that therefore the drugs were accompanied by the booklets, circulars, and leaflets while they were in interstate commerce.

On October 22, 1943, the Economy Hog & Cattle Powder Co., claimant, having admitted the facts in the libel, judgment of condemnation was entered and the printed matter was ordered destroyed and the products were ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS.1201–1250

PRODUCTS

[1] Contains opinion of the court.

[2] Seizure contested. Contains charge to the jury.

SHIPPERS, MANUFACTURERS, AND DISTIBUTORS

[1] Contains opinion of the court.

[2] Seizure contested. Contains charge to the jury.

U. S. GOVERNMENT PRINTING OFFICE: 1945

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to secttion 705 of the Food, Drug, and Cosmetic Act]

1251–1300

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

WATSON B. MILLER, *Acting Administrator, Federal Security Agency.*
WASHINGTON, D. C., *July 9, 1945.*

CONTENTS*

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

1251. Misbranding of Marmola Prescription Tablets. U. S. v. 62 Packages of Marmola Prescription Tablets. Tried to the court. Decree of condemnation and destruction; affirmed on appeal to the Circuit Court of Appeals. Petition for writ of certiorari denied by the Supreme Court. (F. D. C. No. 219. Sample No. 48304–D.)

On April 11, 1939, the United States attorney for the Western District of Wisconsin filed a libel against 62 packages of Marmola Prescription Tablets at LaCrosse, Wis., alleging that the article had been shipped on or about March 17, 1939, by the Raladam Co., from Detroit, Mich.; and charging that it was misbranded. On January 8, 1940, an amended libel was filed.

Examination showed that each tablet of the article contained thyroid, 0.57 grain, extracts of plant drugs including an iodine-containing plant such as bladder-wrack, 0.8 grain, and a laxative drug such as cascara sagrada, flavored with essential oils and ginger.

The article was alleged to be misbranded (1) in that it was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in its labeling; (2) in that its labeling was false and misleading since it falsely represented that the article was a safe and appropriate remedy for obesity, and since it failed to reveal the following facts material with respect to the consequences which might result from the use of the article under the conditions of use prescribed in the labeling, that is, that the article, when taken in the dosage prescribed in the labeling and for the duration

*For failure to bear an accurate statement of quantity of contents, see Nos. 1255, 1261, 1275, 1276, 1292, 1297; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 1275; cosmetic, subject to the drug provisions of the Act, No. 1286.

therein set forth, might cause cardiac irregularities, muscular weakness, endocrine disturbances, and injurious effects resulting from increased metabolism, and might otherwise adversely affect the normal functioning of the human body.

On October 13, 1941, the Raladam Co. having appeared as claimant and filed its answer, the case came on for trial before the court without a jury. At the conclusion of the testimony, the court took the case under advisement and, after consideration of the briefs of counsel subsequently submitted and of the evidence admitted at the trial, handed down, on February 23, 1943, the following memorandum opinion:

STONE, *District Judge*: "This is a libel for condemnation, under the provisions of the Federal Food, Drug & Cosmetic Act of June 25, 1938 (c. 675, 52 Stat. 1040; Title 21 U. S. C. A. § 301 et seq.) of 62 packages of Marmola Prescription Tablets which had been transported in interstate commerce from Detroit, Michigan, to La Crosse, Wisconsin, by the intervener, the Raladam Company. The libel charges that the Marmola Tablets under seizure were misbranded within the meaning of Section 502 (j) of said Act (21 U. S. C. A. 352 (j)) in that the article is dangerous to health when used in the dosage or with the frequency prescribed, recommended or suggested in the labeling thereof, and within the meaning of Sections 502 (a) and 201 (n) of said Act (21 U. S. C. A. 352 (a) and 321 (n)) in that the labeling is false and misleading because it fails to reveal facts material with respect to consequences which may result from the use of the article under the conditions of use prescribed therein.

"The Raladam Company intervened in this action as claimant of the seized article, and answered denying the allegations in the libel, and alleged that Sections 201 (n) and 502 (a) of said Act (21 U. S. C. A. 321 (n) and 352 (a)), were not in force at the time of the alleged violation; that the Federal Food, Drug and Cosmetic Act and each section thereof relied upon by the Government in these proceedings, is unconstitutional for the reasons (a) it provides for unlawful search and seizure; (b) it is too indefinite and uncertain in its provisions; and (c) that said sections contemplate or constitute an unlawful delegation of legislative powers, all in violation of Articles I, II and III of the Constitution of the United States.

"The parties stipulated that the tablets seized had been transferred in interstate commerce; that the Marmola Prescription Tablets contained the following ingredients:

1 grain	Extract Bladderwrack
1/2 grain	Extract Phytolacca
1/4 grain	Extract Cascara Sagrada
	Rx. 87 Spec.
1/2 grain	Desiccated Thyroid
16/1000 min.	Oleoresin Ginger
	Po. Saccharum special
3 grains	Calcium Carbonate Precipitated
1/24 min.	Methyl Salicylate
1/24 min.	Oil Anise
1/24 min.	Oil Sassafras
	Talc Brown
	Ivory Black
	Aqua for Extracts
	Po. Burnt Umber
	Red Oxide of Iron
	Syrupus Simplex
	Lubricating Solution
	Aqua for Granulating
	Liquid Petroleum colorless.

"They further stipulated as follows:

'4. These tablets were manufactured for the Raladam Company by the Arner Company, Inc., from ingredients furnished by Parke, Davis & Company and Parke, Davis & Company has either supplied the active ingredients for or actually manufactured Marmola Prescription Tablets for more than twenty (20) years preceding the commencement of these proceedings, during which period over Twenty Million (20,000,000) packages have been sold by the Raladam Company.

'5. During the past twenty (20) years no change has been made in the ingredients or in the amounts thereof used in Marmola Prescription Tablets except that during the last World War when Cascara Sagrada was tem-

porarily unavailable ¼ grain phenolphthalein was temporarily substituted for the ¼ grain of Cascara Sagrada in the Marmola formula.

'6. The ½ grain of Desiccated Thyroid contained in each Marmola Prescription Tablet is and was at all times during the last twenty (20) years a product of Parke, Davis & Company, and during all of said time all Desiccated Thyroid manufactured and sold by Parke, Davis & Company, which amounts to many millions of grains annually, has contained approximately fifty per cent (50%) more Organic Iodine than the mean average for Desiccated Thyroid as specified in the United States Pharmacopoeia.

'7. The only ingredient of Marmola Prescription Tablets that is involved in this action is the ½ grain of Desiccated Thyroid contained in each tablet.'

"The following provisions of the Federal Food, Drug and Cosmetic Act are involved in these proceedings:

"Section 201, 52 Stat. 1040 (21 U. S. C. A. 321):

'(g) The term "drug" means (1) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any article specified in clause (1), (2) or (3); but does not include devices or their components, parts, or accessories.'

'(n) If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use as are customary or unusual.'

"Section 304 of the Act (21 U. S. C. A. 334), which pertains to the method of seizure and disposition of misbranded food and drugs moving in interstate commerce; and Section 502 (21 U. S. C. A. 352) which reads in part as follows:

'A drug or device shall be deemed to be misbranded—

'(a) If its labeling is false or misleading in any particular.

'(j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.'

"Section 902 of the Act provides for the effective date of the Act, and reads in part:

' * * * That sections 502 (a), 505 and 601 (a), and all other provisions of this Act to the extent that they may relate to the enforcement of such sections, shall take effect on the date of the enactment of this Act * * *'

which was June 25, 1938.

"Section 201 (b) (21 U. S. C. A. 321 (b)) defines interstate commerce as follows:

'The term "interstate commerce" means (1) commerce between any State or Territory and any place outside thereof * * *'

"The labeling involved consists of the printed matter found on the box containing the Marmola Prescription Tablets and in the booklet accompanying same. The portions that are material to the disposition of the issues herein are as follows:

(On Box)

Directions

Take one tablet before each meal and at bedtime with enough water to swallow easily or as directed by a physician. Marmola is recommended *only* as a treatment for adult fat persons whose excess fatness is caused by hypothyroidism with accompanying subnormal metabolic rates but who are otherwise normal and healthy. Marmola should not be taken by persons suffering from any abnormal condition except abnormal excess fat caused as above stated. We make no diagnosis as that is the function of your physician who must be consulted for that purpose. Marmola is not recommended for children. *Before taking be sure to read enclosed circular.*

(In Booklet)

The Purpose of Marmola

Marmola prescription tablets have been sold to the public for more than thirty years and more than twenty million boxes have been distributed during that period. *Marmola* is not sold as a cure-all. It is intended for use only by obese (Obesity is the term used by

the medical profession for an excessive development of fat throughout the body) persons who are otherwise normal and healthy and whose obesity is caused by hypothyroidism with accompanying subnormal metabolism, and our statements and representations made herein or otherwise are strictly limited to this treatment under these conditions and according to the dosage as recommended. We do not make any diagnosis as that is the function of your physician, who must be consulted for that purpose. *Marmola* should not be taken by persons suffering from any abnormal condition except obesity (abnormal excess fat) caused as above stated. The complete formula will be found on page 25. Purchasers who decide or are advised they do not need *Marmola* may obtain refund of the purchase price of any unused package by returning it to the Raladam Company at Detroit.

Important Directions

First.

Take one *Marmola* tablet before each meal and one at bedtime—four a day. Do this regularly.

Second.

For best results we recommend that *Marmola* be used as directed over a period of sixty to ninety days—if needed that long.

Marmola is intended to be used as a week-by-week treatment. The dosage is not intended to cause rapid reduction of weight. Most authorities advise a moderate rate of reduction so the body and skin may adapt themselves to the changed conditions.

The rate of reduction differs with individuals. Habits also affect it. To some results appear rapid, to others slow. No food, drug or other substance which has any physiological effect may be taken internally or applied externally without the possibility of unpleasant or harmful results in some persons if they happen to be constituted so that they do not tolerate the food or other substance. Such a condition can not always be predicted either by physicians or others. If any unpleasant effects are experienced stop taking *Marmola* until they disappear, then resume taking one-half of the former dosage or consult a physician.

How Quick?

Fat reduction under the *Marmola* treatment does not usually start at once. It may take a few days—even up to two weeks—to get things started in the right direction. But the start, when it comes, means much, and it sometimes comes with a spurt. The chief purpose of *Marmola* is to aid in the correction of a deficiency in those obese persons who are otherwise normal and healthy and in whom the lack of the substance supplied by *Marmola* causes the accumulation of excess abnormal fat. The first dose of *Marmola* starts a new supply of this factor, but slowly, so it takes a little time to become apparent. Do not be impatient.

Diet and Exercise

The makers of *Marmola* do not advise abnormal exercise or diet. Extreme measures should not be undertaken. Abnormal exercise in an obese condition may overtax the heart. Starvation diets may lead to a deficiency in vitamins and minerals.

But there is no question that reasonable habits in these respects greatly aid results. Do not throw too great a burden on *Marmola*.

Normal activity, like walking, is suggested but not anything too strenuous without an examination. Moderation in the use of fat-forming foods will aid what you are seeking. But exercise and diet alone cannot be relied upon where there is a deficiency which causes too much food to go to fat. *Marmola* supplies a factor needed in the correction of this deficiency, where the lack of the substance it supplies has caused the accumulation of the abnormal excess fat.

Suggestions

Avoid starches and sweets in excess. Starchy foods include bread and potatoes. Cut down fatty foods. Instead of them eat poultry, eggs, lean meat, clear soups, fish and sea foods. All kinds of fruits and fresh vegetables are good for you. Eat all you want of them. But be sparing of foods with high calory content, like sugar, cereals, and fat. We do not recommend any great self-denial, but simply a reduction of work which *Marmola* is intended to do.

Moderate exercise helps to keep you healthy. Walking is a good exercise. Deep breathing in the open air is good for you, for it supplies oxygen to the blood.

Chew all foods well. At every meal eat a little less than you think you need. These things are suggested to hasten the results you seek, by giving *Marmola* something less to do.

In the 30 years of *Marmola*, it is quite natural that many people who have heard about it, but not used it, may have developed wrong ideas. That is why the complete formula is published in this little book.

The idea that excess fat is always due solely to laziness or gluttony has been dissipated by science. One may be active and eat moderately and still grow fat, if a deficiency exists which causes too much food to be converted into fat instead of energy.

Marmola is a time tested aid to correct this basic cause of the abnormal excessive fat accumulated by reason of the deficiency it is designed to correct. There is no claim to quick and amazing results. A mere hot bath might bring greater quick results by simply draining so much water from the system. But such loss in weight is temporary and unimportant. *Marmola* aims at the basic cause and supplies a deficiency and thus brings real results whenever this deficiency exists. The *Marmola* prescription is compounded by a famous medical laboratory and every ingredient and every percentage has been tested by years of experience.

When to Stop

Stop *Marmola* when your weight comes down to normal. A table in this booklet tells you the average weight of persons of your height and age. Your ideal weight may be either more or less than the average. But you are the best judge of the weight at which

you feel the best and are most efficient. Stop taking *Marmola* as soon as you lose your abnormal excess weight. If, later, you should start to gain again take more *Marmola* tablets until conditions are corrected.

The time required differs with conditions. The use of *Marmola* by those who need it normally results in greater energy and vitality. Our medical advisers do not recommend the taking of *Marmola* as a tonic after the excess fat is gone. This might lead to becoming too thin.. Nor should it be taken if any condition arises which inhibits its use. Consult your physician if any unusual circumstances or conditions arise.

* * * Consult your physician if you want special advice in any unusual condition. We do not make any diagnosis, as that requires personal contact. If you want advice in any special condition or desire more advice than we give you in this book, get it from a physician. We do not prescribe in special cases by letter.

Your doctor, of course, is opposed to self-medication. He may prefer to write his own prescription for some special case, but the *Marmola* prescription has been developed by over 30 years of experience and its efficiency has been tested by the sale of over 20,000,000 boxes throughout the world.

"This case was ably tried by counsel for both parties. Testimony of experts, specialists and investigators, highly qualified in their particular branches of medicine, was submitted by both parties. Voluminous evidence was presented, which included testimony relating to internal medicine, nutrition, chemistry, obesity, endocrinology, thyroid diseases, metabolism, tuberculosis, diabetes, heart diseases, nervous disorders, and many other diseases of the human body. The Government's witnesses included eminent specialists in endocrinology, obesity and thyroid diseases, among whom were Dr. James Short of New York City, a specialist in internal medicine; Dr. Frank Stites of Louisville, Kentucky, a specialist in internal medicine; Dr. Elmer L. Sevringhaus of Madison, Wisconsin, a professor in the medical school of the University of Wisconsin and a specialist in metabolic and endocrine diseases; Dr. Willard O. Thompson, Chicago, professor in the medical school of the University of Chicago and a specialist in endocrinology and metabolism; Dr. Louis H. Newburgh of Ann Arbor, Michigan, a professor in the medical school of Michigan University and a specialist in endocrinology and metabolic diseases; Dr. Israel Bran of Philadelphia, Pennsylvania, a specialist in thyroid diseases. Two members of the staff of Mayo Clinic, Rochester, Minnesota, testified on behalf of the Government. One, Dr. Russell M. Wilder, an instructor in the medical school of the University of Minnesota, is a specialist in the treatment of diabetes; the other, Dr. Samuel F. Haines, is the head of the section of the clinic pertaining to thyroid diseases, and is also an associate professor at the University of Minnesota.

"Other Government witnesses were Dr. William Oatway, Madison, Wisconsin, member of the faculty of the medical school of the University of Wisconsin, and on the staff of the Wisconsin General Hospital in charge of the thoracic services, including tuberculosis; Dr. Chester M. Kurtz of Milwaukee, Wisconsin, also a member of the faculty of the medical school of the University of Wisconsin, and a specialist in heart diseases; Dr. Anton J. Carlson, Chicago, eminent physiologist who had a professorship in the department of physiology at Rush Medical College and the University of Chicago from 1904 until recently when he retired; and Dr. Marian S. Kimble of Madison, a chemist who, as an investigator, made tests as to the value of desiccated thyroid as a remedy for obesity.

"Among those testifying for the intervener were Dr. Abbott W. Allen of New York, assistant clinical professor of medicine of Columbia University; Dr. John A. Killian of Englewood, New Jersey, a biochemist, former instructor of physiology and physiological chemistry at the medical school of Fordham University, and now professor of biochemistry at the New York Post-Graduate School of Columbia University; Dr. Plinn T. Morse of Detroit, Michigan, former instructor in pathology of the University of Michigan and the Detroit College of Medicine, and at present consulting pathologist in Detroit; Dr. William A. Spitzley of Detroit, a general practitioner of wide experience; Dr. Benjamin N. Schlomovitz of Milwaukee, Wisconsin, professor of pharmacology and toxicology at Marquette University Medical School, and a consulting pathologist; and Dr. Andrew I. Rosenberger of Milwaukee, Wisconsin, a specialist in diseases of the nervous system.

"The principal questions before the Court are:

"First: Is the Federal Food, Drug and Cosmetic Act unconstitutional?

"Second: Is the Marmola tablet dangerous to health when used in the dosage or with the frequency and duration prescribed, recommended or suggested in the labeling thereof?

"Third: Is the Marmola labeling false and misleading in the representation that Marmola is a safe remedy for obesity?

"Fourth: Does the labeling reveal facts material with respect to consequences which may result from the use of Marmola under the conditions of use prescribed in the labeling?

"Intervener asserts that the act, and particularly the sections thereof under which these proceedings are brought, are unconstitutional and void because (1) they permit an unlawful search and seizure in violation of the Fourth Amendment to the Constitution of the United States; (2) that the statute and the said sections thereof violate the Fifth Amendment to the Constitution in that they are too indefinite and uncertain to apprise intervener of the offenses attempted to be defined therein; (3) that the statute constitutes an unlawful delegation of legislative powers in violation of Articles I, II, and III of the Constitution of the United States.

"The statute, like its predecessor, was designed to regulate commerce in food, drugs and cosmetics, and to protect the public against foods and drugs that are dangerous to health, as well as those that are falsely branded. It permits the administrative agencies of the Government, charged with its enforcement, to continue to function as under the former act. It is well settled that Congress has the power, under the commerce clause of the Federal Constitution, to condemn the interstate transportation of misbranded drugs, and to make such articles contraband when so transported. *McDermott* v. *Wisconsin*, 228 U. S. 115; *Hipolite Egg Co.* v. *U. S.*, 220 U. S. 45.

"The Fourth Amendment to the United States Constitution does not apply to a seizure process in civil actions. The sections of the act here in question do not provide for unreasonable searches and seizure. This is a civil action as distinguished from a criminal action. It is a proceeding *in rem* and need not be supported by an affidavit of probable cause. *U. S.* v. *Geo. Spraul & Co.*, 185 Fed. 405; *U. S.* v. *Two Barrels of Desiccated Eggs*, 185 Fed. 303.

"Section 502 (j) (21 U. S. C. A. 352 (j)) declares a drug to be misbranded if it is dangerous to health when used in the dosage or with the frequency prescribed in the labeling thereof. The words 'dangerous to health' provide a question of fact for determination by the Court or jury and leave nothing for speculation.

"Section 502 (a) (21 U. S. C. A. 352 (a)) declares a drug to be misbranded if its labeling is false or misleading in any particular. Section 201 (n) (21 U. S. C. A. 321 (n)) defines the scope of Section 502 (a). There is nothing indefinite or ambiguous in Section 201 (n) or 502 (a).

"Proofs under the statute are limited to material facts omitted from the labeling with respect to consequences that may result from the use of the article. The word 'may' is here used in its ordinary sense and signification, there being nothing to show the intention of Congress to affix any other meaning to it. By Section 201 (n) the Government is restricted in its proof to material facts with respect to the consequences that may follow the use of the article; hence there can be no deprivation of intervener's property without due process of law.

"In the act there is no unlawful delegation of legislative power by Congress, nor do the acts of the Government pursuant to the provisions of the statute constitute an exercise of legislative power in violation of the Constitution. Congress may vest discretion in executive officers of the Government to promulgate regulations interpreting the statute even to the extent of providing for penalizing one for a breach of such regulations. *U. S.* v. *Grimaud*, 220 U. S. 506; *Union Bridge Co.* v. *U. S.*, 204 U. S. 364; *Hampton & Co.* v. *U. S.*, 276 U. S. 394.

"In the statute Congress has set up its own policies and standards. There is no delegation of legislative powers to executive officers of the Government. No executive regulations with the force and effect of law are here involved. The statute and the sections thereof involved in these proceedings are well within the powers of Congress to enact and do not violate any part of the United States Constitution or its amendments.

"The Marmola tablets which are offered to the public as a treatment for obesity contain a number of ingredients, but the only one involved in this action is the ½ grain of desiccated thyroid contained in each tablet, and which contains 0.3% organic iodine, which is about 50% more organic iodine than is contained in desiccated thyroid prepared according to the standards of the U. S. Pharmacopoeia. One-third to one-half of the organic iodine in desiccated thyroid consists of thyroxin, which is the active principle of the thyroid hormone secreted by the thyroid gland. The potency of desiccated thyroid is proportional to its organic iodine content, consequently the Marmola tablet produces a greater physiological effect than the same amount of desiccated thyroid prepared according to the standard of the United States Pharmacopoeia.

"The labeling represents that Marmola is intended as a cure for obesity and is for use only by obese persons who are otherwise normal and healthy and whose obesity is caused by hypothyroidism with accompanying subnormal metabolism; that hypothyroidism is the basic cause of obesity which results from a lack of

a substance which Marmola supplies. The daily dosage recommended is equivalent to two grains of desiccated thyroid containing 0.3% organic iodine, or to three grains of desiccated thyroid containing 0.2% organic iodine, prepared according to the standard of the United States Pharmacopoeia.

"Obesity is defined as an excessive development or excessive storage of fat throughout the body. There is a difference of opinion among the experts who testified as to the cause of obesity and its remedy. Some of the Government witnesses testified that overweight is caused by excessive eating and lack of proper exercise; that the weight may be reduced by dietary measures coupled with adequate exercise. Some of claimant's witnesses testified that a large proportion of cases of obesity are caused by endocrine disturbances or disorders; that the thyroid gland is the regulator of the metabolic processes and that obesity is due at least in a large part to a deficient activity in this gland, and hence in its treatment thyroid medication is necessary. Other witnesses were of the opinion that obesity is caused both by overeating and by endocrine disturbance.

"Hypothyroidism is a word which denotes the underfunctioning of the thyroid gland, which is a condition of disease. It is accompanied by a subnormal basal metabolic rate and by other symptoms, such as dryness of skin, scarcity of hair and eyebrows, sluggishness of physical and mental reactions, decreased appetite, slower pulse rate and characteristic changes in the composition of the blood, and, in advanced stages of hypothyroidism or myxedema, by puffy and swollen appearance of the face and other parts of the body due to a collection of mucoid fluid beneath the skin.

"By metabolism is meant the total of the various processes by which food is transformed in the body into the chemicals which are absorbed into the blood stream and lymphatic system for the purpose of nourishing the body so that it can carry on its work. The health of the body depends upon the well-balanced use of the body chemicals. Metabolism denotes all the processes of the body by which food is used, body heat and energy created, and the body built up or repaired, and by which the tissues of the body are destroyed and waste matter excreted.

"The rate of metabolism is measured by the rate at which the body produces or gives off heat. The 'basal metabolic rate' is defined as the least rate of chemical activity which will maintain the absolutely essential functions of the body sufficiently to keep an individual alive. Every activity of the body increases the amount of energy consumed. Having found the basal requirements of an individual, the physician can, by the addition of the demands of the individual's other activities, compute what his total needs will be. Average normal standard rates have been established by tests, and the results are expressed in terms of either plus or minus variations from the standard. In the same classification normal healthy people vary one from another in the normal basal metabolic rate. The great majority vary only to the extent of 10% more or 10% less in the amount of heat produced, represented by the average normal standard. Normal healthy people may vary from the average standard normal rate to even a greater extent, but seldom more than 15% more or less than standard, which means that the individual is consuming 15% more or 15% less energy than the average among normal people.

"Desiccated thyroid is used in the treatment of hypothyroidism, and the optimum dosage in such treatment must be determined for each individual case. It varies with each individual and is established only by trial and error. The optimum daily dosage may be as little as ¼ grain per day, and in most cases less than 2 grains per day, although there are some cases that exceed 2 grains per day, depending upon the underfunctioning of the individual's thyroid gland.

"There was a substantial agreement among the medical witnesses that the overdosage of desiccated thyroid results in an increase in the metabolism of the patient; that it has a toxic effect on people that are hypothyroid in that it increases their basal metabolic rate and injuriously affects the functioning of the endocrine glands, kidney and liver, impairing their capacity for normal functioning; that it places an extra burden on the organs of the body; that it results in symptoms which cannot be distinguished from those disclosed in spontaneous hyperthyroidism, such as rapid heart, heart pains, shortness of breath, sleeplessness, nervous and emotional instability, headaches, dizziness, tremor, muscular weakness, disturbances of the alimentary canal, fatigue, nausea, and, in women, menstrual disturbances; that the symptoms of hyperthyroidism will disappear days or weeks after the discontinuance of desiccated thyroid, but it sometimes results in the precipitation of a more serious and permanent disease and injury to health; that many people who consider themselves normal and

healthy, and who are completely unaware that they are suffering from any hidden disease, have been found to have physical impairments or diseases in a mild or incipient form such as impairment of the heart, diabetes, or tuberculosis, which may be discovered only by thorough examination by an experienced physician; that in such cases a dosage of two grains of desiccated thyroid a day aggravates the disease or ailment or accelerates the onset of their more serious phases. This fact was established by the testimony of experts and investigators learned in endocrinology and familiar with the physiological manifestations of thyroid, based on their study, experience, and clinical observations. Dr. Short testified that many people have heart ailment and are completely unaware of it; that he made a study of 2,400 male persons who were supposedly healthy, which he placed in three groups. The first group included those who had normal hearts according to the electrocardiogram. There were 811 in this group. Group 2 included 1,330 persons who had borderline impairments that might or might not be significant of heart disease. Group 3 included 250 persons who had a very definite impairment of the heart. In group 2, 90% had no symptoms and were unaware of any possible heart ailment. In group 3, those having definite impairment, 87% had no symptoms and were unaware of heart injury.

"Dr. Russell M. Wilder testified that many people have diabetes and are unaware of it; that the records of the Mayo Clinic for the year just preceding the date of his appearance as a witness herein, showed that of approximately 100,000 patients received at the Clinic, about 1,700 were suffering from diabetes; that about ⅕ of the 1,700 came to the Clinic without any knowledge that they had this disease; that desiccated thyroid is definitely harmful to a diabetic; that when a person develops hyperthyroidism, his diabetes is invariably aggravated.

"Dr. Oatway testified that many people have tuberculosis and are unaware of it; that from his investigations and tests he discovered that 9/10 of those suffering from active tuberculosis were unaware of it.

"The medical testimony was substantially all to the effect that in sound medical practice a doctor will prescribe thyroid for hypothyroidism only after a careful physical examination is made of the patient's head, eyes, throat, chest, lungs, heart, abdomen, and reflexes covering the nervous system of the patient to ascertain if the patient is suffering from any latent or underlying disease of which he is unaware, such as diabetes, tuberculosis, or heart ailment. In some instances a basal metabolism is done, x-rays of the chest are made, and an electrocardiogram of the heart is obtained.

"Any drug, which for safety in its use required diagnosis and evaluation, and when taken in the dosage and with the frequency recommended and suggested in its labeling, may expose the users to disease and pain, is dangerous to health. Marmola is such a drug. In it there is an inherent and potential danger that may reasonably be expected to attend its use when one considers that it will be used by the strong, the weak, the old, the young, the well, and the sick, without first having a physical examination or a diagnosis of their condition by a competent physician.

"Obesity is not caused by hypothyroidism. Those suffering from hypothyroidism are sometimes over-weight due to the deposit in the body of a mucoid substance which is not fat and which desiccated thyroid may remove under proper treatment. Desiccated thyroid may stimulate the appetite and its use may result in increased weight unless the dosage is so large as to result in hyperthyroidism, which is a disease.

"Obesity is not affected materially by the use of Marmola prescription tablets as prescribed or by desiccated thyroid of comparable daily dosages, except by producing and maintaining a condition of hyperthyroidism. The discontinuance of Marmola on the appearance of unpleasant effects or unusual circumstances or conditions does not avoid danger. When these effects or conditions appear, the user is in a state of hyperthyroidism, which, in some cases, may result in the precipitation of more serious and permanent injury.

"The substantial portion of the public, after reading the labeling in question, would conclude that obesity is caused by the lack of some substance in the human body that Marmola supplies; that Marmola is a safe and efficient remedy for obesity, which is not a fact. The labeling fails to inform the prospective user that if he is suffering from hypothyroidism, he is not healthy and normal. It places a duty upon the user to make a self-diagnosis to determine if he is suffering from hypothyroidism. The layman lacks familiarity with medical terminology. He has little or no knowledge of medical science, and does not possess that skill and learning required to determine whether he is suffering from hypothyroidism. The labeling does not recommend that an obese person considering the use of

Marmola should first consult a physician. It does advise that he consult a physician if he desires special advice in any unusual condition or more advice than appears on the label. It suggests that the doctor is opposed to self-medication and might prefer to write his own prescription.

"The Federal Food, Drug and Cosmetic Act was not made for experts, nor is it intended to prevent self-medication. The purpose of the law is to protect the public, the vast multitude which includes the ignorant, the unthinking, and the credulous who, when making a purchase, do not stop to analyze. It was enacted to make self-medication safer and more effective, and to require that drugs moving in interstate commerce be properly labeled so that their use as prescribed may not be dangerous to the health of the user. It should receive a liberal construction. *U. S.* v. *Lee*, 131 F. 2d 464; *Florence Mfg. Co.* v. *Dowd Mfg. Co.*, 178 F. 73; *Aronberg* v. *Federal Trade Commission*, 132 F. 2d 165.

"The administration of thyroid tablets in Marmola dosages is a dangerous procedure, and should not be undertaken without a thorough examination of the prospective user by a competent physician, and then only under the supervision of the doctor.

"The Court is thoroughly convinced, by a preponderance of the evidence, that Marmola, when used as prescribed in the labeling thereof, is neither a safe, appropriate, nor an efficient remedy for obesity; that it is dangerous to the health of the user when used in the dosage or with the frequency and duration prescribed, recommended or suggested in the labeling thereof; that the packages of Marmola in question, when seized in these proceedings, were misbranded within the meaning of the sections of the Federal Food, Drug and Cosmetic Act involved herein; that the labeling on Marmola is false and misleading in its representations that it is a safe remedy for obesity, and in that it fails to reveal facts material with respect to consequences which may result from the use of Marmola under the conditions prescribed in the labeling.

"The contention of the intervener that the sections of the act involved in these proceedings were not in force at the time of the seizure of the Marmola packages is disposed of by Section 902. It is clear from the reading of that statute that these sections were in force at the time of the commencement of these proceedings.

"The libellant is entitled to a decree of condemnation as prayed for in the libel, with costs, and other proper expenses to be taxed against the intervener."

In accordance with the foregoing opinion there were filed findings of fact and conclusions of law, and on April 7, 1943, judgment of condemnation was entered and the product was ordered destroyed. On June 22, 1943, the case was appealed to the United States Circuit Court of Appeals for the Seventh Circuit, and on May 4, 1944, the following opinion was handed down by that court, affirming the judgment of the District Court:

LINDLEY, *District Judge:* "Claimant seeks to reverse a judgment condemning 'Marmola' drug tablets entered in a proceeding under the Federal Food, Drug & Cosmetic Act (c. 675, 52 Stat. 1040; Title 21 U. S. C. A., sec. 301 *et seq.*) The essential averments of the libel were that the tablets were misbranded in that (1) when used as prescribed they are dangerous to health; (2) they are falsely represented to be a safe and appropriate remedy for obesity, and, (3), the instructions for use fail to reveal facts material with respect to the consequences which may arise upon the use of the drug as prescribed, thus violating Section 502 (a), 502 (j) and 201 (n) of the Act (1).

"The Government complained of the printed matter on the packages and in the circulars accompanying them. The directions on the box read: 'Take one tablet before each meal and at bedtime with enough water to swallow easily or as directed by a physician. Marmola is recommended only as a treatment for adult fat persons whose excess fatness is caused by hypothyroidism with accompanying subnormal metabolic rates but who are otherwise normal and healthy. Marmola should not be taken by persons suffering from any abnormal condition except abnormal excess fat caused as above stated. We make no diagnosis as that is the function of your physician who must be consulted for that purpose. Marmola is not recommended for children. Before taking be sure to read the enclosed circular.'

"The instructions in the circular are more detailed; only the part which it is necessary to consider is quoted:

* * * Marmola is not sold as a cure-all. It is intended for use only by obese (obesity is the term used by the medical profession for an excessive development of fat throughout the body) persons who are otherwise normal and healthy and whose obesity is caused by hypothyroidism with accompanying subnormal metabolism, and our statements and representations made herein or otherwise are strictly limited to this treatment under

these conditions and according to the dosage as recommended. We do not make any diagnosis as that is the function of your physician, who must be consulted for that purpose. Marmola should not be taken by persons suffering from any abnormal condition except obesity (abnormal excess fat) caused as above stated.

Important Directions

First

Take one Marmola Tablet before each meal and one at bedtime—four a day. Do this regularly.

Second

For best results we recommend that Marmola be used as directed over a period of sixty to ninety days—if needed that long.

* * *

* * * No food, drug or other substance which has any physiological effect may be taken internally or applied externally without the possibility of unpleasant or harmful results in some persons if they happen to be constituted so that they do not tolerate the food or other substance. Such a condition can not always be predicated either by physicians or others. If any unpleasant effects are experienced stop taking Marmola until they disappear, then resume taking one-half of the former dosage or consult a physician.

Suggestions

* * * The idea that excess fat is always due solely to laziness or gluttony has been dissipated by science. One may be active and eat moderately and still grow fat, if a deficiency exists which causes too much food to be converted into fat instead of energy. Marmola is a time-tested aid to correct this basic cause of the abnormal excessive fat accumulated by reason of the deficiency it is designed to correct.

When to Stop

* * * But you are the best judge of the weight at which you feel the best and are most efficient. Stop taking Marmola as soon as you lose your abnormal excess weight. If, later, you should start to gain again take more Marmola tablets until conditions are corrected.

* * * Consult your physician if any unusual circumstances or conditions arise. Your doctor, of course, is opposed to self-medication. He may prefer to write his own prescription for some special case, but the Marmola prescription has been developed by over 30 years of experience and its efficiency has been tested by the sale of over 20,000,000 boxes throughout the world.

"Our essential question is whether the evidence is such as to justify us in saying as a matter of law that the District Court's finding that Section 502 (j) of the Act has been violated because Marmola tablets, when used in the dosage and with the frequency and for the duration prescribed, recommended or suggested in their labeling, are dangerous to health is erroneous. Obviously the finding should not be set aside unless clearly against the weight of the evidence. Rule 52 (a) Rules of Civil Procedure, 28 U. S. C. A. following Section 723: *Sauder* v. *Dittmer* (CCA10), 118 F. 2d. 524; *United States* v. *State Street Trust Co.*, (CCA1), 124 F. 2d 948; *Super Mold Corporation of California* v. *Bacon*, (CCA9), 130 F. 2d. 860; *Stork* v. *Townsend*, (CCA6), 132 F. 2d. 859; *Wertz* v. *National City of Evansville, Ind.*, (CCA7), 115 F. 2d. 65, cert. den. 311 U. S. 675.

"Claimant has sold this medical concoction for more than thirty years as a reducing aid for persons whose obesity is supposed to be caused by hypothyroidism and have an accompanying subnormal metabolism. 'Hypothyroidism,' resulting from under-functioning of the thyroid gland, is accompanied by a subnormal metabolic rate and such symptoms as dryness of the skin, scarcity of hair and eyebrows, sluggishness of physical and mental reactions, decreased appetite, slower pulse rate and characteristic changes in the composition of the blood, and, in advanced stages, by a puffy and swollen appearance of the face and other parts of the body due, not to increased fatty tissue but to mucoid fluid deposited beneath the skin. 'Metabolism' denotes the sum total of all processes of the human body by which food is transformed into chemicals in turn absorbed into the blood stream and lymphatic system for the purpose of so nourishing the body that it can continue to function. In other words, it is the aggregate of all processes whereby food is digested, heat and energy created, the body built up or repaired and waste matter excreted. By examination of the rates at which normal persons give off heat, scientists have established the normal rate of metabolism from which, experience has revealed, most persons deviate by not more than 10 per cent. To enjoy good health, one's body must maintain a proper balance of essential chemicals; the thyroid gland is the primary

agency in achievement of this end. Excess of the thyroid hormone in the blood stream results in hyperthyroidism and too little hypothyroidism.

"The only ingredient of the condemned drug with which the proceeding was concerned is the desiccated thyroid included in the formula. This is derived from the thyroid glands of hogs and sheep, and has the same effect upon one's physical make-up as the hormones produced by a human gland. The potency of desiccated thyroid is roughly proportional to its iodine content. The product here contains approximately 0.3% of organic iodine and thus possesses one and one-half times the potency of that made in accord with the standard of the U. S. Pharmacopoeia.

"Qualified authorities and specialists in medicine, chemistry and nutrition, supplied testimony, somewhat in conflict, relating to the cause and 'cure' for obesity, hypothyroidism and hyperthyroidism and to metabolism, as well as proof of the effect of thyroxin upon persons suffering from Graves' Disease, heart disease, amenorrhea and psychoneuroses. The evidence discloses that an over-dosage of desiccated thyroid produces hyperthyroidism. Indeed, as to this there can be no question, since such medication supplies an excess of the hormone. The record also reveals that medical men are in agreement that one person's tolerance for the drug may be a great deal less than another's. Claimant recognizes this, too, since, in the circular, it warns, 'No food, drug or other substance which has any physiological effect may be taken internally or applied externally without the possibility of unpleasant or harmful results in some persons if they happen to be constituted so that they do not tolerate the food or other substance. * * * If any unpleasant effects are experienced stop taking Marmola until they disappear * * *.'

"Medical witnesses testified as to further effects of overdosage, such as increased metabolism of the patient, injuriously affecting the functioning of the endocrine glands, kidneys and liver; impairment of bodily functions because of the extra burden placed upon human organs: symptoms which can not be distinguished from those peculiar to hyperthyroidism, such as rapid heart, heart pains, nervous and emotional instability, nausea, menstrual disturbances; serious aggravations which result in persons who consider themselves normal and healthy, but are actually subject to such latent diseases as heart disease, diabetes, tuberculosis, when they use desiccated thyroid. Indeed, their testimony is largely to the effect that a daily dosage of two grains a day is dangerous to health. Lay witnesses gave vivid reports of the effect of the tablets upon their health. Weakness, heart palpitations, amenorrhea, emotional nervous states, and domestic difficulties were described as aftermaths of the use of the tablets. One witness reduced her weight from 165 pounds to 95 pounds, then ceased to take the tablets, but continued to lose until she weighed only 50 pounds. The testimony of toxic effect of desiccated thyroid in prescribed Marmola dosage was conflicting. Clinical tests by Dr. Killian and Dr. Allen, in which the amount of the hormone were greatly increased, were said to reveal no harmful and lasting results.

"We think the evidence such as to justify only the conclusion reached by the trial court. We certainly are not justified in saying that the finding is erroneous as a matter of law. Admittedly, taking four tablets a day, is not dangerous to the health of all users, since tolerance for the drug varies; but the experience of various witnesses, all of whom took tablets according to the directions on the label, as well as the testimony of the number of medical experts, inevitably impels one to the finding that use of the tablets as prescribed is dangerous to the health of the public. The fact that some users may be able to tolerate greater quantities, as the experiments conducted by Dr. Killian and Dr. Allen tend to show, does not militate against the conclusions, for Section 502 (j) does not require that the drug must be dangerous to the health of all who take it in the dosage and for the duration prescribed or recommended. It devolved upon the trial court to determine only whether it was proved that the drug is dangerous to the public health at large if used as recommended by its vendors. *U. S.* v. *Lexington Mill & Elevator Co.*, 232 U. S. 399.

"The trial court further found the tablets subject to condemnation under Section 502 (a), in that they were misbranded because they were falsely represented to be a safe and appropriate remedy for obesity, when in fact they are not, for the reason that obesity is not caused by the lack of any substance which Marmola supplies; and, under Section 201 (n), in that the labels did not reveal facts material with respect to possible consequences of use of the tablets under the conditions prescribed, since the instruction to discontinue use of the tablets upon appearance of 'unpleasant effects' does not prevent the occurrence of more

serious symptoms as a result of the hyperthyroidic condition previously precipitated. It is unnecessary to discuss these findings, since the judgment must be sustained for violation of Section 502 (j). For the same reason, we find it unnecessary to consider other contentions regarding Sections 502 (a) and 201 (n).

"Claimant makes much of the proposition that the legislative history of the Federal Food, Drug & Cosmetic Act discloses that Congress had no intent to deprive individuals of the right of self-medication. This we think beyond the point, for the decision of the lower court deprives no one of this right. It merely determines that Marmola tablets are dangerous to the public health when used in the dosage and with the frequency prescribed by claimant. What would be a non-deleterious prescription was not agreed upon by the experts and was not within the province of the court to decide.

"The judgment is affirmed."

The claimant subsequently filed a petition for a writ of certiorari with the Supreme Court of the United States, and on October 9, 1944, that petition was denied.

1252. Misbranding of Marmola Tablets. U. S. v. 23 Dozen Packages (276 packages) of Marmola Tablets (and 10 other seizure actions against Marmola Tablets). Decrees of condemnation and destruction. (F. D. C. Nos. 9885, 9886, 12731, 12732, 12744, 12755, 12756, 12812, 12820, 12830, 12831. Sample Nos. 8016–F, 8017–F, 8747–F, 48582–F, 48584–F, 59378–F, 59379–F, 68211–F, 75374–F, 77654–F, 77655–F, 78227–F, 81812–F.)

Between May 3, 1943, and July 13, 1944, the United States attorneys for the District of Minnesota, the Western District of Kentucky, the Southern District of Indiana, the Eastern and Western Districts of Pennsylvania, the District of Connecticut, and the Northern District of Illinois filed libels against the following quantities of Marmola Tablets: 276 packages at St. Paul, Minn.; 34 packages at Minneapolis, Minn.; 105 packages at Louisville, Ky.; 384 packages at Indianapolis, Ind.; 428 packages at Philadelphia, Pa.; 105 packages at Pittsburgh, Pa.; 43 packages at New Haven, Conn.; and 282 packages at Chicago, Ill. On July 5, 1944, an amended libel was filed against the lot at Louisville, to cover the seizure of a total of 144 packages at that place. It was alleged in the libels that the article in the Minneapolis lot had been shipped on or about April 14 and 22, 1943, by the Walgreen Co., from Chicago, Ill.; and that the article in the other lots had been shipped between the approximate dates of February 15, 1943, and June 16, 1944, by the Raladam Co., from Detroit, Mich.

Examination of samples showed that the article contained plant material, including an extract from a laxative plant drug, and thyroid in amounts varying from 0.67 to 0.75 grain per tablet.

The article was alleged to be misbranded in that it was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in its labeling.

Between November 3 and December 18, 1944, pursuant to agreement between the Raladam Co., claimant, and the attorneys for the Government, based on the appellate court's decision in the case of the *United States* v. *62 packages of Marmola Prescription Tablets*, as reported in notices of judgment on drugs and devices, No. 1251, judgments were entered condemning the product and ordering its destruction.

1253. Misbranding of UtraJel. U. S. v. Pynosol Laboratories, Inc., Edwin G. Melich, and James J. Melich. Pleas of guilty. Corporation fined $1,000; individual defendants each fined $1. (F. D. C. No. 7289. Sample Nos. 14773–E, 54628–E, 54631–E, 79056–E, 84825–E, 92548–E, 92549–E.)

On May 6, 1943, the United States attorney for the Northern District of Illinois filed an information against Pynosol Laboratories, Inc., Chicago, Ill., and Edwin G. Melich, and James J. Melich, president and secretary-treasurer, respectively, of the corporation, alleging shipment of a quantity of UtraJel between the approximate dates of October 17, 1941, and April 18, 1942, from the State of Illinois into the States of Pennsylvania, Kentucky, New York, and California.

Analysis showed that the article consisted essentially of a soap, pine oil, combined iodine, and water, with the exception of one portion which consisted essentially of soap, pine oil, and water.

The article was alleged to be misbranded because of false and misleading statements on the tube and carton and in the circular entitled "Directions For Use," which accompanied all lots, regarding its efficacy in the treatment of minor infections of the cervix and cervical canal, cervical erosions, and cystic conditions of the cervix; and in the circular entitled "UtraJel Indicated as an aid,"

which accompanied a portion of the product, regarding its efficacy in stimulating infected areas and in eliminating the danger of infections. The article was alleged to be further misbranded in that the following statements on the tube and carton, "UtraJel * * * as a uterine evacuant * * *," and in the circular entitled "Directions For Use," "UtraJel * * * As A Uterine Evacuant * * * UtraJel has been used successfully for induction of labor in full term deliveries, and for the expulsion of either entire or parts of placenta," and in the circular entitled "UtraJel Indicated as an aid," "UtraJel * * * as a uterine evacuant * * * As a Uterine Evacuant UtraJel may be used as an aid in legal therapeutically indicated cases, premature and full term. * * * UtraJel in many cases, eliminates the necessity of surgery," were false and misleading since the article would not be safe and appropriate for introduction into the uterine cavity but was unsafe and capable of producing serious and even fatal consequences.

The article was alleged to be misbranded further in that it was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling.

The defendants having filed a motion to quash on July 15, 1943, and that motion having been denied on November 1, 1943, pleas of guilty were entered and the court, on April 20, 1944, imposed fines of $1,000 against the corporation and $1 against each of the individual defendants.

1254. Misbranding of procaine hydrochloride. U. S. v. 1 Package, 8 Packages, and 19 Packages of Procaine Hydrochloride. Default decrees of condemnation and destruction. (F. D. C. Nos. 11679, 11682. Sample Nos. 56892–F, 56893–F, 65986–F.)

On or about January 21 and 27, 1944, the United States attorneys for the District of New Jersey and the District of Connecticut filed libels against the following quantities of the above-named product: 1 package containing 10 ampuls at Elizabeth, N. J., and 8 packages containing 100 ampuls each, and 19 packages containing 10 ampuls each at Middletown, Conn.; alleging that the article had been shipped between the approximate dates of October 14 and December 13, 1943, by the Loeser Laboratory, Inc., from New York, N. Y.; and charging that it was misbranded. The article was labeled in part: "No. 401 [or "405"] * * * Procaine Hydrochloride * * * Loeser Laboratory, Inc. New York, N. Y. Subsidiary of the Wm. M. Merrell Company."

The article was alleged to be misbranded in that the statements in its labeling, "Procaine Hydrochloride, U. S. P. 200 mg. [or "50 mg."]," were false and misleading since the amount of procaine hydrochloride in each ampul was not only greatly in excess of that declared on the label, but there was an excessive variation between the quantity present in the individual ampuls. The article was alleged to be misbranded further in that it was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling, i. e., "for spinal anesthesia by admixture with spinal fluid * * * To be used only by or on the prescription of a physician."

On March 6 and 25, 1944, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

1255. Adulteration and misbranding of procaine hydrochloride solution, with epinephrine. U. S. v. 38 Packages of Procaine Hydrochloride Solution (and 3 other seizure actions against procaine hydrochloride solution). Default decrees of condemnation and destruction. (F. D. C. Nos. 12348, 12407, 12509, 12774. Sample Nos. 35967–F, 35968–F, 50975–F, 63447–F, 75324–F, 75349–F.)

Between the approximate dates of May 10 and June 28, 1944, the United States attorneys for the Northern District of Georgia, the Eastern District of Pennsylvania, and the Northern District of Ohio filed libels against the following amounts of procaine hydrochloride solution: 52 packages, each containing 25 cartridges, at Atlanta, Ga.; 38 packages, each containing 25 cartridges, at Philadelphia, Pa.; and 200 cartridges at Youngstown, Ohio; alleging that the article had been shipped between the approximate dates of March 8 and May 15, 1944, by A. Pfingst and Pfingst & Co., New York, N. Y.; and charging that it was adulterated and misbranded. The article was labeled in part: "Procaine Hydrochloride [or "HCl"] Solution 2% with Epinephrine."

The article was alleged to be adulterated in that its purity and quality fell below that which it purported to possess since the article was not sterile, but was contaminated with living micro-organisms.

The article was alleged to be misbranded in that it was dangerous to health when used in the dosage suggested in the labeling thereof, that is, when the

contents of the cartridge were injected into the tissues. A portion of the article was alleged to be further misbranded in that it failed to bear a label containing an accurate statement of the quantity of the contents of the package. The label of this portion bore no statement of the quantity of the contents of each cartridge.

Beween May 29 and July 26, 1944, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

1256. Misbranding of sulfathiazole tablets. U. S. v. Samuel S. Punsky (Franklin Pharmacy). Plea of nolo contendere. Fine, $1,000. Execution of sentence suspended and defendant placed on probation for 1 year. (F. D. C. No. 10605. Sample Nos. 20577–F, 20698–F, 20701–F.)

On December 15, 1943, the grand jurors for the District of Maine returned an indictment against Samuel S. Punsky, trading as the Franklin Pharmacy, Portland, Maine, alleging that a number of bottles of sulfathiazole tablets had been shipped from the State of New York into the State of Maine on or about November 13, 1942. It was charged in the indictment that on or about December 24, 1942, one bottle of the article, which was in the same condition as when shipped in interstate commerce, was sold and delivered to the defendant; that on or about August 24, 25, and 26, 1943, and while a number of tablets of the article contained in the aforesaid bottle were being held for sale after shipment in interstate commerce, the defendant removed a number of tablets from the bottle, repacked them in unlabeled boxes, and disposed of the boxes of tablets by sale; and that those acts of removal, repacking, and disposal resulted in the tablets being misbranded since the boxes containing them bore no directions for use.

On December 28, 1943, the defendant having entered a plea of nolo contendere, the court imposed a fine of $1,000 which was suspended, and placed the defendant on probation for 1 year.

1257. Adulteration of Stero-Uteroids and misbranding of Natur-Pep. U. S. v. Lloyd M. Curts and Charles D. Folse (Curts-Folse Laboratories). Pleas of guilty. Fine, $200. (F. D. C. No. 8831. Sample Nos. 2642–F, 3045–F, 3548–F, 3549–F.)

On July 14, 1943, the United States attorney for the District of Kansas filed an information against Lloyd M. Curts and Charles D. Folse, copartners trading as the Curts-Folse Laboratories, Kansas City, Kans., alleging shipment of a quantity of the above-named products from the State of Kansas into the State of Missouri from on or about March 27 to November 16, 1942.

The article known as Stero-Uteroids was alleged to be adulterated in that its purity fell below that which it purported or was represented to possess since, by reason of its name, it purported and was represented to be a sterile product, whereas it was not a sterile product, but was contaminated with viable pathogenic micro-organisms, *Clostridium tetani*.

Analysis of the Natur-Pep disclosed that the article consisted essentially of Epsom salt (30.9 percent), water, and small amounts of iron phosphate, sodium and potassium compound, methenamine, a salicylate, and extracts of plant drugs including a laxative plant drug. The article was alleged to be misbranded (1) because of false and misleading statements in its labeling which represented and suggested that it was not habit forming; that it possessed tonic properties which would increase pep; that it would restore health, cleanse and stimulate the lining of the stomach and cause the gastric juices to flow freely, increase the flow of bile, bring back the vigorous feeling so essential to happiness, flush out the excess poisons that accumulate in the tiny tubes of the kidneys, and give complete relief from bladder irritation, weakness, "night rising," and other miseries such as dizziness, spots before the eyes, loss of pep, puffiness under the eyes, and stiffness in the back and lower limbs; that it was an hematinic tonic for the blood; that it would restore deficient red blood cells, cure constipation, regulate the bowels, and strengthen or tone soft, weak, and flabby intestinal muscles: and that it would be efficacious in the treatment of nervous, weak, and rundown conditions, poor appetite, swollen limbs, and stiff joints; (2) the statement on its label, "Natur-Pep Tonic Is Prepared From Ingredients of Recognized Medicinal value: Extract Cascara Sagrada Iron Pyrophosphate Strontium Salicylate Oleum Coriandar Methyl Salicylate Extract Gentian Alcohol ½% Hexamethylenamine Extract Glycyrrhiza Magnesium Sulphate Potassium Acetate Sodium Salicylate Oleum Anise Glycerine," was misleading since it suggested and created the impression that the article contained therapeutically significant quantities of each and every one of the ingredients named, whereas the article

contained therapeutically unimportant quantities, if any, of the ingredients named in the statement, with the exception of magnesium sulfate (Epsom salt); (3) its labeling failed to bear adequate directions for use since the directions suggested continuous administration of the article, whereas the article was a laxative and should not be administered continuously; and (4) its labeling failed to warn that the article should not be taken when nausea, vomiting, abdominal pain, or other symptoms of appendicitis are present, or that frequent or continued use of the article might result in dependence upon a laxative to move the bowels.

On April 3, 1944, the defendants having entered pleas of guilty, the court imposed a fine of $100 on each of 2 counts, a total fine of $200.

1258. Misbranding of Perry's Famous Peptone Pills and of another drug known as Natura, Nu-Vita, or Vita. U. S. v. Victor Edison Perry (V. E. Perry). Plea of guilty. Sentence of 3 months' imprisonment suspended, and defendant placed on probation for 1 year. (F. D. C. No. 11387. Sample Nos. 22653–F, 22779–F, 22868–F, 23606–F, 46323–F, 58424–F.)

On May 31, 1944, the United States attorney for the Eastern District of Pennsylvania filed an information against Victor Edison Perry, trading as V. E. Perry, Philadelphia, Pa., alleging that the defendant shipped and caused to be shipped quantities of the above-named drugs between the approximate dates of March 23 and November 9, 1943, from the State of Pennsylvania into the States of New Jersey, Delaware, Maryland, and Virginia, and from the State of New York into the State of Pennsylvania.

Analysis disclosed that the Peptone Pills consisted essentially of damiana, nux vomica, zinc phosphide, calcium carbonate, starch, sugar, and coloring; and that the other product known as Natura, Nu-Vita, and Vita consisted essentially of Epsom salt, sulfur, sodium bicarbonate, and plant material including senna and cascara sagrada.

The article Peptone Pills was alleged to be misbranded (1) in that its name was misleading since it represented and implied that the article would be efficacious to restore and maintain pep and tone in the user, whereas it would not be efficacious for such purposes; (2) because of false and misleading statements and a design consisting of a picture of a bald-headed old man dancing with a young woman, which represented and suggested that the article would be efficacious to restore and maintain pep and tone in man, correct or cure weak nature and low courage, build up men 100 percent, and restore youthful vigor in old men; and that it would be efficacious in the treatment of worn-out, rundown, slow, sluggish, or low manhood, or weak vitality; and (3) in that it contained strychnine, and its label did not bear a statement of the quantity or proportion of strychnine contained therein.

The article Peptone Pills was alleged to be misbranded further because of false and misleading statements and designs in circulars entitled "Nature Means in Mexico New Life," "Are You Dizzy," and "Natura Will Help You Face the Bitter Winter With 100% Health," which accompanied the article, and which represented and suggested that another drug, "Natura," consisted solely of Mexican herbs and possessed the rejuvenating and health-giving properties implied in the expression "New Life"; and that it would be efficacious in the cure, mitigation, treatment, or prevention of high blood pressure, low blood pressure, sore back, rheumatism, backache, getting up nights, constipation, uric acid poisons, impure blood, headache, rough skin, pimples on the face, swollen tonsils, swollen and stiff joints, and catarrh; that Natura was a world-famous tonic, a wonder herb tonic, and the world's greatest spring tonic; that all sickness is caused by excess uric acid poisons; that Natura would maintain and restore perfect health and pep, would be of special value to persons over the age of thirty, would insure pure red blood, and would help the user to face the cold and hardships of winter with 100 percent health; and that it would be efficacious to reduce ugly fat and make the body beautiful, help clean the blood, and help destroy such symptoms of high and low blood pressure as dizzy, swimming head, nervous, short naps, tiredness, and sleeplessness.

The article bearing the names "Nu-Vita New Life [or "Vita"] Wonder Mexico-America Herb Powder," and "Natura New Life Wonder Mexico-America Herb Powder," was alleged to be misbranded (1) in that the names were false and misleading since they represented and implied that the article consisted solely of herbs; and that it possessed the rejuvenating and health-giving properties implied in the names, whereas it consisted in part of the mineral substances, Epsom salt, sulfur, and sodium bicarbonate, and did not possess the rejuvenating and health-giving properties implied in the names; (2) because of false and misleading statements and a design of an Indian scene with the legend "Picking

Wonder Herb Tea," on the labels, which represented and suggested that the article was a spring and summer tonic; that it was an herb preparation and would be efficacious to clean the blood; that it would be of special value to persons over the age of thirty, and that it would be efficacious in the cure, mitigation, treatment, or prevention of stomach distress due to excess acid, indigestion, headache, gas, constipation, rheumatism, and the various similar conditions indicated by the abbreviation "etc."; (3) in that its labeling failed to bear adequate directions for use since the directions appearing on the labels suggested and implied that the article should be taken continuously, whereas it was a laxative and continuous use might cause dependence on laxatives to move the bowels; and (4) in that the labeling failed to bear warnings that frequent or continued use might result in dependence upon laxatives to move the bowels.

A portion of the article known as "Natura" and "Nu-Vita" was alleged to be misbranded further because of false and misleading statements in the labeling which represented and suggested that it would be efficacious in the cure, mitigation, treatment, or prevention of dizziness from high and low blood pressure, in the treatment of backache, and in the prevention of getting up nights; and that another article, "Gen Sen," would be efficacious in the purification of the blood, and in the cure, mitigation, treatment, or prevention of high blood pressure, rheumatism, backache, getting up nights, child bed wetting, and swollen feet.

On June 16, 1944, the defendant entered a plea of guilty and the court imposed a sentence of 3 months' imprisonment, which was suspended, and placed the defendant on probation for a period of 1 year.

1259. Misbranding of Nervine, Q. B. Tonic, I-Do-Lax, Q. B. Skin Aid, Sen-San Diuretic Compound, Equine Antimalarial, and Veterinary Specific. U. S. v. J. W. Quinn Drug Co. and John W. Quinn. Pleas of nolo contendere. Corporate defendant fined $50 on count 1, which was to be paid; also $100 on each of the remaining 6 counts, which was suspended. Imposition of sentence against individual defendant was indefinitely suspended. (F. D. C. No. 10618. Sample Nos. 5851-F to 5853-F, incl., 5856-F, 5857-F, 9441-F, 9447-F.)

On March 23, 1944, the United States attorney for the Northern District of Mississippi filed an information against the J. W. Quinn Drug Co., a corporation, Greenwood, Miss., and John W. Quinn, president of the corporation, alleging shipment of quantities of the above-named products between the approximate dates of April 14, 1942, and January 30, 1943, from the State of Mississippi into the States of Tennessee and Louisiana.

Analysis of the Nervine disclosed that it was a light brown, aromatic, slightly turbid, salty liquid, consisting essentially of ammonium, potassium, and sodium bromides. The article was alleged to be misbranded because of false and misleading statements and designs in an accompanying circular which represented and suggested that the article would enable the user to sleep soundly and to become packed with energy; that it contained no substances which might be harmful; that it would be efficacious in the treatment of irritability and nervousness due to worry, overwork, and overexcitement; that it would preserve health, make one healthy, prevent sleepless nights, overcome a tired, lazy, no-good, run-down feeling, and enable the user to get a full, sound night's sleep and awake feeling refreshed.

Analysis of the Q. B. Tonic disclosed that it was a yellow, transparent liquid containing 1.84 grams per 100 ml. of quinine as quinine bisulfate, together with iron, magnesium, and nitrate. The article was alleged to be misbranded because of false and misleading statements in an accompanying circular which represented and suggested that the article would give the user energy, overcome laziness, and enable the user to sleep better; that it would be efficacious in the treatment of aches and pains in the back and legs, and in the cure, mitigation, treatment, or prevention of feverish or run-down conditions; and that it would improve the appetite and make the user feel energetic and strong.

Analysis of the I-Do-Lax disclosed that it was a clear, dark brown liquid, having a salty, slightly astringent taste, and consisting essentially of Epsom salt, potassium iodide, and iron chloride. The article was alleged to be misbranded because of false and misleading statements on its labels and false and misleading statements and a design in an accompanying circular which represented and suggested that the article would be efficacious in the treatment of disorders of the blood; that it would enable the user to overcome a run-down, tired, weak, and achy feeling; that it would be efficacious in the treatment of headaches, circles under the eyes, nervousness, gas and bloating, dry skin, backache, physical weakness, burning, smarting, itching, leg pains, swollen ankles, dizziness, loss of vigor, acidity, disturbed digestion, bladder weakness, and getting

up nights; and that it would be useful for treating diseases generally. The article was alleged to be misbranded further (1) in that the name "I-Do-Lax" was false and misleading since it represented and implied that the article was an effective laxative when used as directed, "One tablespoonful in water 3 times a day," whereas the article contained insufficient laxative ingredients to constitute it an effective laxative when used as directed; and (2) in that its labeling was misleading since it failed to reveal the fact that it contained but a small proportion of magnesium sulfate (Epsom salt), which fact was material in the light of the representation on its labels, "Iodide of Potash Compound with Iron and Magnesium Sulfate."

Analysis of the Q. B. Skin Aid disclosed that it was a clear, greenish yellow, volatile liquid having an aromatic and phenolic odor, and consisting essentially of carbolic acid, alcohol, salicylic acid, benzoic acid, menthol, and eucalyptol. The article was alleged to be misbranded because of false and misleading statements on its labels and in an accompanying circular which represented and suggested that the article would allay irritation of the skin, promote healing, and would be efficacious in the treatment of skin ailments generally; that it would rapidly kill fungi, help clean healing, and guard against and ward off infection; that it would be efficacious in the treatment of eczema itch, skin irritations, and painful sunburn; and that it would soothe the skin. The article was alleged to be misbranded further in that it contained carbolic acid, and its labeling failed to bear a warning that it might cause harmful effects if applied to the fingers or toes and bandaged, or if applied to large areas of the body.

Analysis of the Sen-San Diuretic Compound disclosed that it was a dark brown liquid containing 0.235 gram per 100 ml. of salicylic acid, together with senna, sodium, and citrate. The article was alleged to be misbranded because of false and misleading statements on its label and in an accompanying circular which represented and suggested that it would help the kidneys in their necessary action of elimination; that it would be efficacious in the treatment of frequent urination or burning on urination, kidney ailments, gas and bloating, physical weakness, circles under the eyes, swollen ankles, leg pains, dizziness, and loss of vigor; and that it would be of value in the treatment or prevention of headache, puffy eyes, legache, nervousness, backache, tiredness, loss of pep, getting up nights, or the complications resulting therefrom. The article was alleged to be misbranded further in that its labeling failed to bear adequate directions for use since the directions in its labeling suggested and implied that it should be taken continuously, whereas it was essentially a laxative and should be taken only occasionally, as needed.

Analysis of the Equine Antimalarial disclosed that it was a saline solution containing sodium cacodylate equivalent to 44.4 grains anhydrous sodium cacodylate per 15 cc. ampul, or about 60 grains sodium cacodylate N. F. VII. The article was alleged to be misbranded because of false and misleading statements on its labels which represented and suggested that it would be efficacious in the cure, mitigation, treatment, or prevention of malaria in horses, mules, and cattle.

Analysis of the Veterinary Specific disclosed that it was a clear liquid containing chloral hydrate, potassium bromide, and the alkaloids strychnine and arecoline. The article was alleged to be misbranded because of false and misleading statements on its labels which represented and suggested that it would be efficacious in the cure, mitigation, treatment, or prevention of gas and water colic in horses, mules, and cows; and in that its labeling did not bear appropriate directions and adequate warnings that it should not be administered over a long period of time.

On April 26, 1944, pleas of nolo contendere having been entered on behalf of the defendants, the court fined the corporate defendant $50 on count 1, which was paid. The court also fined the corporation $100 on each of the remaining 6 counts, but suspended payment. Imposition of sentence of the individual defendant was suspended indefinitely.

1260. Adulteration and misbranding of Pep-O-Sol Tablets, and misbranding of Vital-X Spray. U. S. v. Clarence A. Near (Near Chemical Co.). Plea of guilty. Fine, $100. (F. D. C. No. 11423. Sample Nos. 8169–F, 8170–F.)

On July 10, 1944, the United States attorney for the District of Minnesota filed an information against Clarence A. Near, trading as the Near Chemical Co., Minneapolis, Minn., alleging shipment of quantities of the above-named products from the State of Minnesota into the State of Wisconsin on or about June 5 and July 19, 1943.

Analysis of the Pep-O-Sol Tablets disclosed that the article contained oxyquinoline sulfate, boric acid, and a sugar, and, when diluted as recommended, was devoid of antiseptic properties. The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess, since it was represented to be an antiseptic whereas it was not an antiseptic within the meaning of the law in that it was not a germicide when used in the dilutions recommended in its labeling, and it did not purport to be and was not represented as an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body. It was alleged to be misbranded because of false and misleading statements in an accompanying circular entitled "Near's Stockmen News," which represented and suggested that the article, when used as directed in the drinking water of baby chicks, growing birds, turkeys, and laying flocks, and other livestock, would make the drinking water antiseptic; that the article was a powerful antiseptic; that it would increase pep in poultry, give chicks improved health, cause faster growth, greater vitality, and quicker development; that its use would obviate danger of infection; that it would control disease germs and protect chicks from disease; and that it would be efficacious to keep the intestinal tract clear of infection, aid digestion, and furnish blood-building elements that are necessary for health and vitality.

Analysis of the Vital-X Spray disclosed that it consisted essentially of eucalyptol, camphor, menthol, creosote, turpentine, chloroform, a phenolic substance such as guaiacol, and a saponifiable oil. The article was alleged to be misbranded (1) because of false and misleading statements in the circular accompanying the article, which represented and suggested that it would be efficacious in the cure, mitigation, treatment, or prevention of roup, colds, flu, gapes, bronchitis, and pneumonia in fowls; (2) in that its label failed to bear a statement containing the name of any of the ingredients of the article; and (3) in that its labeling failed to bear any directions for use.

On July 10, 1944, the defendant entered a plea of guilty, and the court imposed a fine of $100.

1261. Misbranding of Dr. Holland's Cow Cathartic, Mineralized Medicated Stock Salt, and Liquid Gall Kure. U. S. v. The Holland Stock Remedy Co. and Alan R. Branson. Pleas of guilty. Fine of $250 and costs against each defendant. (F. D. C. No. 11339. Sample Nos. 798–F, 22098–F, 46808–F, 53172–F.)

On February 3, 1944, the United States attorney for the Northern District of Ohio filed an information against the Holland Stock Remedy Co., a corporation, Wellington, Ohio, and Alan R. Branson, president and treasurer of the corporation, alleging shipment of quantities of the above-named products between the approximate dates of April 16 and September 9, 1943, from the State of Ohio into the States of Michigan, Pennsylvania, Indiana, and Virginia.

Analysis of the Cow Cathartic disclosed that it consisted essentially of Epsom salt and plant material, including nux vomica (containing strychnine) and ginger. The article was alleged to be misbranded because of false and misleading statements on the label which represented and suggested that disorders of the digestive organs are the most common ailments of cattle; that the article would be efficacious in the cure, mitigation, treatment, or prevention of disorders of the digestive organs of cattle, indigestion, scours, suppression of milk, bloat, and causes of strong smelling, bad tasting, ropy milk; and that the article could be always administered safely to a sick cow. It was alleged to be further misbranded in that its label bore no statement of the quantity of the contents; and in that it contained strychnine and its label did not bear a statement of the quantity or proportion of strychnine contained in the article.

Analysis of the Mineralized Medicated Stock Salt disclosed that it consisted essentially of salt and small proportions of sulfur, charcoal, plant material, and compounds of calcium, iron, and phosphorus. The article was alleged to be misbranded because of false and misleading statements in its labeling which represented and suggested that it would be efficacious in the cure, mitigation, treatment, or prevention of worms, indigestion, or scours and pin worms in horses, contagious abortion in cows, hog cholera, and worms in lambs and sheep; that it was "Medicated," i. e., that it contained ingredients, other than salt, in therapeutically important amounts; that it was effective as a poultry tonic, and would produce good results in the raising of poultry; that it would increase the quantity and improve the quality of milk; and that it would keep animals healthy and enable them to resist disease. It was alleged to be further misbranded in that it was recommended for administration to rabbits, foxes, and other small

animals, and its labeling did not bear adequate directions for administration to such animals.

Analysis of the Gall Kure disclosed that it was a solution of methylrosanilin. The article was alleged to be misbranded because of false and misleading statements in its labeling which represented and suggested that it would be efficacious in the cure, mitigation, treatment, or prevention of galls and sore teats in cows; that it was the best remedy known for all abrasions of the skin on man or beast; that it would be efficacious to purify and heal all kinds of sores, including galls, and open wounds, and all irritated or inflamed surfaces caused by saddle, collar, harness, or hobbles; that it would be efficacious to cause healing of all inflammations, burns, skin irritations, hives, poison ivy, and similar conditions indicated by the abbreviation "etc.," and to cause healing of harness galls, sores, cuts, wire fence jags, sore heels, sore mouths, and similar conditions, indicated by the abbreviation "etc.," on horses, mules, and other animals; that it would produce the effects of violet rays; and that another article, Medicated Stock Salt, would be efficacious as an animal tonic and conditioner, and as a preventative and destroyer of worms. It was alleged to be further misbranded in that its label bore no statement of the quantity of the contents; and in that it did not bear the common or usual name of the article, i. e., "Solution of Methylrosanilin."

On March 1, 1944, pleas of guilty having been entered on behalf of the defendants, the court imposed a fine of 250 and costs against each defendant.

1262. Misbranding of Oripahs. U. S. v. 58 Packages and 220 Packages of Oripahs. Default decree of condemnation and destruction. (F. D. C. No. 11844. Sample Nos. 46730–F, 54809–F.)

On February 19, 1944, the United States attorney for the Eastern District of Wisconsin filed a libel against 58 packages, 20-capsule size, and 220 packages, 40-capsule size, of Oripahs, at Milwaukee, Wis., alleging that the article had been shipped on or about September 20, 1943, by Oripahs, Chicago, Ill.; and charging that it was misbranded.

Analysis of a sample of the article showed that the capsules contained boric acid, phenolphthalein (0.26 grain per capsule), and a laxative plant drug such as rhubarb.

The article was alleged to be misbranded (1) in that its name and the statements in the leaflet entitled "Oripahs," enclosed in the retail carton, which represented and implied that the article was to be used for the reduction of body weight were false and misleading since the article was not effective for that purpose; (2) in that the statements on the label, "No Dinitrophenol No Thyroid," which implied that the article was a safe and effective treatment for the reduction of body weight were false and misleading since the article was not safe and effective for that purpose; (3) in that its labeling failed to bear adequate directions for use, since the article, when taken as directed, provided for a full dose of phenolphthalein, i. e., one grain, and an additional quantity of the laxative ingredient rhubarb, whereas the article was essentially a laxative and should have been taken only occasionally, as needed, and not continuously, as recommended; and (4) in that its labeling failed to warn that frequent or continued use might result in dependence on laxatives to move the bowels, and that the preparation should be discontinued if a skin rash appeared.

On March 29, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1263. Misbranding of Special Compressed Tablets. U. S. v. 96,000 Special Compressed Tablets. Consent decree ordering the release of the product under bond. (F. D. C. No. 10510. Sample No. 48443–F.)

An agreement existed between the shipper and consignee of this product that it was to be repackaged. When repackaged, however, the labeling contained therapeutic claims that constituted misbranding.

On August 31, 1943, the United States attorney for the Northern District of Ohio filed a libel against 96,000 Special Compressed Tablets at Cleveland, Ohio, alleging that the article had been shipped on or about June 9, 1943, by Charles H. Dietz, Inc., St. Louis, Mo.

The article was labeled in part: "Special Compressed Tablet RX2742 Each C. T. contains: Caffeine Alkaloid . . . ¼ gr. Acetphenetidin . . . 2½ grs. Aspirin . . . 3½ grs. Tinct. Gelsemium . . . 2 Min." Examination showed that the article had essentially the composition declared on its label.

The article was alleged to be misbranded (1) in that its labeling failed to bear adequate directions for use; and (2) in that its labeling failed to warn that frequent or continued use of an article containing acetophenetidin may

be dangerous, causing serious blood disturbances, and that not more than the recommended doses should be taken.

On November 22, 1943, the Jones Surgical Supply Co., Cleveland, Ohio, claimant, filed an answer alleging that the label which was used by it in repackaging the product bore the required warnings, but admitting that the repackaged goods bore words that the Government claimed did constitute misbranding. On the same date the claimant having consented to the entry of a decree, judgment was entered finding that the labels used by the claimant constituted misbranding, and ordering that the product be released under bond, conditioned that it be relabeled with labels approved by the Food and Drug Administration.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

1264. Adulteration of calcium gluconate with dextrose. U. S. v. Lloyd M. Curts and Charles D. Folse (Curts-Folse Laboratories). Pleas of guilty. Fine, $100. (F. D. C. No. 10594. Sample No. 3366–F.)

On December 29, 1943, the United States attorney for the District of Kansas filed an information against Lloyd M. Curts and Charles D. Folse, copartners trading as the Curts-Folse Laboratories, Kansas City, Kans., alleging shipment of a quantity of the above-named product from the State of Kansas into the State of Missouri on or about February 8, 1943.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported or was represented to possess since it purported or was represented to contain 23 percent of calcium gluconate, whereas it contained not more than 16.32 percent of calcium gluconate.

On April 3, 1944, the defendants having entered pleas of guilty, the court imposed a fine of $100.

1265. Adulteration and misbranding of nicotinic acid tablets. U. S. v. Armour & Co. (Armour Laboratories). Plea of nolo contendere. Fine, $100 and costs. (F. D. C. No. 10545. Sample No. 2375–F.)

On September 22, 1943, the United States attorney for the Northern District of Illinois filed an information against Armour & Co., a corporation trading under the name of Armour Laboratories, Chicago, Ill., alleging shipment of a quantity of the above-named product on or about March 11, 1943, from the State of Illinois into the State of Indiana.

The article was alleged to be adulterated in that it purported to be and was represented as nicotine acid tablets, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from and its quality fell below the official standard since the Pharmacopoeia provides that nicotinic acid tablets shall contain not less than 95 percent of the labeled amount of nicotinic acid, whereas the article contained not more than 80.94 percent of the labeled amount of nicotinic acid, and its difference in strength and quality from the official standard was not plainly stated on its label.

The article was alleged to be misbranded in that the statement on its label, "Each Tablet Contains 50 Milligrams Nicotinic Acid," was false and misleading since the article contained not more than 40.47 milligrams of nicotinic acid.

On November 9, 1943, a plea of nolo contendere having been entered on behalf of the defendant, the court imposed a fine of $50 on each of 2 counts, a total fine of $100 and costs.

1266. Adulteration of dandelion root. U. S. v. 98 Bags of Dandelion Root. Default decree of condemnation and destruction. (F. D. C. No. 11952. Sample No. 65557–F.)

On March 4, 1944, the United States attorney for the Eastern District of Michigan filed a libel against 98 bags of dandelion root at Detroit, Mich., alleging that the article had been shipped on or about January 31, 1944, by the Western Trading Co., Portland, Oreg.; and charging that it was adulterated.

The article was alleged to be adulterated in that it purported to be and was represented as dandelion root, a drug the name of which is recognized in the National Formulary, an official compendium, but its quality and purity fell below the official standard since the Formulary requires that vegetable drugs are to be as free as practicable from molds, insects, or other animal life and animal excreta, whereas the article was infested with live larvae, and contained a large amount of larval excreta and webbing.

On April 24, 1944, no claimant having appeared, judgment of condemnation was entered and the article was ordered destroyed.

*See also Nos. 1255, 1257, 1260.

1267. Adulteration of oil of lemon. U. S. v. 4 Barrels of Oil of Lemon (and 1 other seizure action against oil of lemon). Consent decree of condemnation. Product ordered released under bond. (F. D. C. Nos. 9962, 10317. Sample Nos. 11304–F, 11326–F to 11328–F, incl.)

On May 19 and July 30, 1943, the United States attorney for the Northern District of California filed libels against the following quantities of oil of lemon at San Francisco, Calif.: 4 55-gallon barrels, 4 drums, each labeled as containing 393 pounds (or other weight), 2 385-pound drums, and 13 cases, each containing 2 25-pound cans; alleging that the article had been shipped by Standard Synthetics, Inc., from New York, N. Y., from on or about August 24, 1942, to April 2, 1943; and charging that it was adulterated. A portion, 4 drums, was labeled in part, "Oil Lemon Baja Brand." The remainder was labeled in part: "Oil Lemon Baja Brand U. S. P.," "Oil Lemon Baja Brand," or "Oil of Lemon Baja Brand," the last 2 lots having been invoiced as U. S. P. oil of lemon.

The article, with the exception of the 4-drum lot, was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from and its quality and purity fell below the standard set forth therein since the article was a distillate or mixture of distillates of lemon oil, and not lemon oil obtained by expression from the peel of the lemon.

The article was also alleged to be adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

On February 16, 1944, the libel proceedings having been consolidated and removed to the Eastern District of New York for trial, and Standard Synthetics, Inc., claimant, having admitted the allegations of the libels, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

1268. Adulteration of Koagamin. U. S. v. 1,000 Units of Koagamin (and 3 other seizure actions against Koagamin). Decrees of condemnation. Portion of product ordered released under bond; remainder ordered destroyed. (F. D. C. Nos. 11449, 11450, 11599, 11600. Sample Nos. 29636–F, 29637–F, 29639–F, 29640–F.)

Between December 16, 1943, and January 13, 1944, the United States attorneys for the Eastern District of Missouri and the District of Colorado filed libels against 2,000 vials and 2,100 boxes, each containing 6 vials, of Koagamin at St. Louis, Mo., and against 1,000 units and 1,000 boxes, each containing 6 vials, of the product at Denver, Colo.; and on January 31, 1944, the libel against the 2,000-vial lot was amended to describe the amount as 2,000 boxes, each containing 6 vials, of the product. It was alleged in the libels that the article, which had been consigned by Chatham Pharmaceuticals, Inc., had been shipped from Newark, N. J., on or about November 23 and December 18, 1943.

The article was alleged to be adulterated in that its purity and quality fell below that which it purported and was represented to possess, i. e., "Intramuscular or Intravenous Injection," since it was not suitable for parenteral use because of contamination with undissolved material.

On January 31 and February 11, 1944, no claimant having appeared for two of the lots, judgments of condemnation were entered and the product was ordered destroyed. On March 2 and 10, 1944, Chatham Pharmaceuticals, Inc., claimant, having admitted the allegations of the libels against the other two lots, judgments of condemnation were entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

1269. Adulteration and misbranding of tincture of Hyoscyamus. U. S. v. 21 Bottles of Tincture of Hyoscyamus. Default decree of condemnation and destruction. (F. D. C. No. 12302. Sample No. 23757–F.)

On May 2, 1944, the United States attorney for the Eastern District of Pennsylvania filed a libel against 21 1-pint bottles of the above-named product at Philadelphia, Pa., alleging that the article had been shipped on or about June 7, 1943, by the Elvita Research Laboratories, Inc., from New York, N. Y.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from the official standard, which provides that tincture of Hyoscyamus shall contain in each 100 cc. not less than 0.0034 gram of the alkaloids of Hyoscyamus, and not less than 65 percent of alcohol. The article was found to contain not more than 0.0028 gram of the alkaloids of Hyoscyamus in each 100 cc., and approximately 55.9 percent of alcohol.

It was alleged to be misbranded in that the statements on the label, "Tincture of Hyoscyamus U. S. P. XI * * * Alcohol, 68% by volume * * * 100 c. c.

Represent: 0.0040 Gm. of the Alkaloids of Hyoscyamus," were false and misleading.

On May 29, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1270. Adulteration and misbranding of Ophthalets Epinephrine-Procaine Comp. U. S. v. 20 Boxes of Opthalets Epinephrine-Procaine Comp. Default decree of condemnation and destruction. (F. D. C. No. 12373. Sample No. 55132-F.)

On May 16, 1944, the United States attorney for the Eastern District of Michigan filed a libel against 20 boxes, each containing 100 capsules, of the above-named product at Detroit, Mich., alleging that the article had been shipped between the approximate dates of January 27 and May 28, 1943, by the McNeil Laboratories, Inc., Philadelphia, Pa.; and charging that it was adulterated and misbranded.

The article consisted of gelatin-coated capsules containing an opthalmologic ointment which was to be applied directly into the eye by clipping the tip end of the capsule and squeezing out the contents. Examination showed that the ointment contained not more than 1.30 percent of procaine.

The article was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess, "Procaine * * * 2.5%."

The article was alleged to be misbranded in that the statement on the label, "Procaine * * * 2.5%," was false and misleading.

On June 15, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1271. Adulteration and misbranding of Duchex. U. S. v. 18¼ Dozen Packages of Duchex. Default decree of condemnation and destruction. (F. D. C. No. 11998. Sample No. 67414-F.)

On March 13, 1944, the United States attorney for the Northern District of Ohio filed a libel against 18¼ dozen packages of Duchex at Cleveland, Ohio, alleging that the article had been shipped on or about February 9, 1944, by Hachmeister, Inc., Pittsburgh, Pa.; and charging that it was adulterated and misbranded.

Examination showed that the article consisted essentially of sodium bicarbonate, chloramine-T approximately 15 percent, and menthol. Bacteriological tests showed that the article was not a germicide.

The article was alleged to be adulterated in that its strength and quality differed from that which it purported and was represented to possess, i. e., germicidal.

The article was alleged to be misbranded because of certain false and misleading statements in its labeling which represented and suggested that it was a germicide and would be effective in the cure, mitigation, treatment, or prevention of vaginal acidosis, nervousness, irritability, leucorrhea, pains of menstruation, and other physiological complications.

On June 24, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1272. Adulteration and misbranding of sutures. U. S. v. 89 Packages and 42 Packages (1,572 tubes) of Sutures (and 3 other seizure actions against sutures). Default decrees of condemnation and destruction. (F. D. C. Nos. 11992, 12226, 12412, 12856. Sample Nos. 52177-F, 52179-F, 52593-F, 58476-F, 58477-F, 58493-F, 76775-F, 81625-F.)

Between March 13 and July 3, 1944, the United States attorneys for the District of Columbia, the Eastern District of New York, and the District of Massachusetts filed libels against the following quantities of sutures: 1,572 tubes at Washington, D. C., 8,640 tubes and 3,432 tubes at Brooklyn, N. Y., and 144 tubes at Brookline, Mass.; alleging that the article had been shipped on or about October 14, November 15 and 20, and December 28, 1943, from Chicago, Ill., by the Salvus Products, Inc.; and charging that it was adulterated and misbranded. The article was labeled in part: "Salvus Sutures * * * Salvus Products Inc. Biochemists," or "Salvus Sutures * * * Davis & Pitann Ltd. Biochemists Chicago."

The article was alleged to be adulterated in that it purported to be and was represented as catgut sutures, a drug the name of which is rceognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth therein since it was not sterile, but was contaminated with viable micro-organisms.

The article was alleged to be misbranded in that the statements in its labeling,

"Heat Sterilized," and "Catgut, USP," or "Catgut Sutures USP," were false and misleading.

Between April 24 and August 15, 1944, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

1273. Adulteration of prophylactics. U. S. v. 9 5/12 Gross of Prophylactics. Default decree of destruction. (F. D. C. No. 11969. Sample No. 67035–F.)

On or about March 9, 1944, the United States attorney for the Western District of Missouri filed a libel against 9 5/12 gross of prophylactics at North Kansas City, Mo., alleging that the article had been shipped on or about February 24, 1944, from San Francisco, Calif., by the Aronab Products Co.; and charging that it was adulterated.

Examination of 60 samples taken from the above-mentioned shipment disclosed that 10, or 16.7 percent, were defective in that they contained holes.

The article was alleged to be adulterated in that its strength and quality fell below that which it purported or was represented to possess since an article containing holes is not suitable for use as a prophylactic.

On April 19, 1944, no claimant having appeared, judgment was entered ordering that the product be destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

DRUGS FOR HUMAN USE

1274. Misbranding of Caladin. Two informations: U. S. v. John P. Michieli (J. P. Michieli). Plea of not guilty to count 1, and plea of guilty to count 2 of both informations. Count 1 of both informations tried to a jury; verdict of guilty. Sentence on count 1 of each information, $250 and 30 days in jail in the event of nonpayment of fines; count 2, 2 years' probation. (F. D. C. Nos. 7281, 7725. Sample Nos. 63458–E, 94543–E.)

On August 6 and November 16, 1942, the United States attorney for the Northern District of California filed informations against John P. Michieli, trading as J. P. Michieli, San Francisco, Calif. On February 11, 1943, the informations were amended pursuant to a stipulation entered into between the Government and the defendant. It was alleged in the informations that the defendant had shipped, on or about January 12 and May 4, 1942, from the State of California into the States of Oregon and Illinois, quantities of Caladin which was misbranded.

Analysis of a sample disclosed that the article consisted essentially of calcium chloride, hydrochloric acid, a small proportion of iodine, and water.

The article was alleged in count 1 of both informations to be misbranded because of false and misleading statements on the bottle labels which represented and suggested that the article would stimulate an alkaline balance in the blood and tissues, restore the nerves affected to normal working order, give full nerve supply to the ductless glands, organs, and muscles; and that it would effect cures in cases heretofore held incurable, whereas it would not accomplish the results suggested and implied.

Count 1 of one information charged the article to be misbranded further because of false and misleading statements in an accompanying booklet which represented and suggested that the article would raise low blood pressure to normal, and lower high blood pressure to normal; that it would have a better curative effect on the heart than any other treatment medical science could offer; that it would cause repeated alkaline reaction in the blood and tissues; that it would obviate increased heart action by preventing the dissolution of the calcium content in the nerve cells; that it would prevent the infiltration of magnesium oxide into the nerve cells; that it would remove a diseased condition of the heart and restore it to an improved state of health; that it would clean out chemical impediments from the nerve cells, and cause the nerves to supply the organs and ductless glands with the nerve energy necessary to bring their function back to working order; that it would give lasting benefits in medication of the heart, that it would cause the individual suffering from heart trouble to feel stronger; that it would repair the heart; that it would obviate the need of a wheelchair and narcotics in cases of paralysis resulting from arthritis; that the statements on the label and in the booklet with respect to the article were based on sufficient knowledge of medicine and of biological and general chemistry to guard the interest of the physician and patient; that

*See also Nos. 1251, 1253, 1254, 1257–1262, 1265, 1269–1272.

the article would reestablish the chemical balance in the blood and tissues of the body; that use of the article was the only effective treatment for high blood pressure; that it would benefit persons suffering from high or low blood pressure within a period of one month or earlier; that the article, in raising low blood pressure and reducing high blood pressure, would not raise low blood pressure above normal nor reduce high blood pressure below normal; that it would cure and prevent slowed-down blood circulation and dropsy; that it was a chemical compound of far-reaching curative merit; that it would improve puny children so that even the school report cards of the children would show higher marks; that the article would cause the magnesium oxide in the nerve cells involved to be dissolved and replaced by calcium, and would restore the conductivity of the nerves; that it would cause to be generated the full amount of insulin necessary to neutralize the excess sugar in the blood; that insulin injections could be reduced safely or discontinued entirely, and the regular diet could be resumed safely by use of the article; that it would be beneficial for use in all cases of convalescence; that it would eliminate the necessity for nature's aid in the cure, mitigation, treatment, or prevention of all organic functional disturbances and all germ-caused diseases; and that it would be efficacious in the cure, mitigation, treatment, or prevention of diseases of the heart and other organic and functional disorders, including arthritis, heart trouble resulting from chemical changes in the nerve cells due to exertion in athletics, enlargement of the heart and damaged heart, arthritis of the spine, paralysis resulting from arthritis, heart disease due to high blood pressure, angina pectoris, diseases of the stomach, liver, and kidneys, slowed-down brain activity, rheumatism, neuritis, menopause, deficient or profuse menstruation, anemia, high and low blood pressure, general debility and weakness of the aged, diabetes, tuberculosis, troubles of the prostate gland, sinus trouble, nervous breakdown, disturbed gland action in puny children, hardening of the arteries, diseases which physicians are unable to diagnose and which do not respond to prescribed treatment, and all organic functional disturbances, and all germ-caused diseases.

The article was alleged in count 2 of both informations to be misbranded further in that its label failed to bear the common or usual names of the active ingredients of the article.

On June 22, 1943, the defendant having entered pleas of not guilty on count 1 and guilty on count 2, and the cases having been consolidated, trial was had before a jury on the issues involved in count 1. On June 29, 1943, the jury returned a verdict of guilty, and on July 1, 1943, the court imposed the following sentences: Count 1, $250 and 30 days in jail in the event of the nonpayment of the fine; count 2, probation for a period of 2 years.

1275. Misbranding of Sinu-Vita Emulsion, Sinu-Vita No. 1, Sinu-Vita Inhalant, and Sinu-Vita No. 2. U. S. v. Herman D. Seekamp (Sinu-Vita Co.). Plea of nolo contendere. Fine, $100. (F. D. C. No. 11389. Sample Nos. 32017–F to 32020–F, incl.)

On May 15, 1944, the United States attorney for the Eastern District of Missouri filed an information against Herman D. Seekamp, trading as the Sinu-Vita Co., St. Louis, Mo., alleging shipment of a quantity of the above-named products on or about February 19, 1943, from the State of Missouri into the State of Indiana.

Analysis of a sample of the Sinu-Vita Emulsion showed that it consisted of a dark brown, turbid liquid containing water, unidentified dextrins and sugars, small amounts of volatile oils including peppermint and eucalyptus, and wood creosote. The article was alleged to be misbranded (1) because of false and misleading statements on its label which represented and suggested that it would be efficacious in the cure and treatment of pneumonia, flu, and similar conditions, germ diseases, whooping cough, deep-seated coughs, tuberculosis, bronchitis, sore throat, and malaria; and (2) because of false and misleading statements in blue and buff circulars accompanying the article which represented and suggested that, when used alone or in conjunction with "Sinu-Vita Inhalant," it would be efficacious in the treatment and prevention of pneumonia, tuberculosis, and bronchitis, infection of the lungs or other area, head colds, cuts, burns, dark circles under the eyes, sunken cheeks, sallow complexion, rose and hay fever, tuberculosis of the throat and bones, large red blotches on the legs, tuberculous blotches, difficult breathing, daily elevation of temperature, lost strength, lost weight, pulmonary tuberculosis, and sinus infection; and that it would be efficacious to destroy tubercle bacilli; and to cause the diseased tissue to separate from the healthy tissue so that it could be coughed up and cause the lung to heal.

Analysis of the Sinu-Vita No. 1 showed that it consisted of a green, clear liquid containing, chiefly, unidentified saponifiable fixed oil and small amounts of pepper-

mint, eucalyptus, sassafras, turpentine, and lavender oils, and a minute amount of a phenolic substance resembling wood creosote. It was alleged to be misbranded (1) because of false and misleading representations on its label regarding its efficacy in the treatment of sinus headaches, head colds, and sore throat; and (2) because of false and misleading representations in pink, blue, and buff circulars, and in an order blank, regarding the efficacy of the article in the treatment of failing eyesight, pleurisy, sinus infection, affections of the nose and throat, pulmonary tuberculosis, infection of the lungs or other area, lost strength, lost weight, head colds, cuts, burns, dark circles under the eyes, sunken cheeks, sallow complexion, rose and hay fever, tuberculosis of the throat and bones, red blotches on the legs, tuberculous blotches, difficult breathing, and daily elevation of temperature; and representations that it would be efficacious to destroy tubercle bacilli, and to cause diseased tissue to separate from healthy tissue so that it could be coughed up and cause the lung to heal.

Analysis of the Sinu-Vita Inhalant disclosed that it consisted of a green, clear liquid containing, chiefly, a saponifiable fixed oil and small amounts of eucalyptus, sassafras, lavender, peppermint, and turpentine oils, a small amount of a phenolic material resembling wood creosote, and a minute amount of undissolved sodium sulfate. It was alleged to be misbranded because of false and misleading statements appearing in its labeling which represented and suggested that it would be efficacious in the cure, mitigation, treatment, or prevention of sinus headache, head colds, sore throat, tuberculosis, bronchitis, affection of the lungs, pleurisy, sinus disease, pneumonia, affection of the bronchi and lungs, infection of the lungs or other area, cuts, burns, dark circles under the eyes, sunken cheeks, sallow complexion, rose and hay fever, tuberculosis of the throat and bones, large red blotches on the legs, tuberculous blotches, difficult breathing, daily elevation of temperature, lost strength, lost weight, pulmonary tuberculosis, and sinus infections; and that it would be efficacious to destroy tubercle bacilli, and to cause the diseased tissue to separate from the healthy tissue so that it could be coughed up and cause the lung to heal.

Examination of Sinu-Vita No. 2 disclosed that it consisted of a small bottle and a small tin box. Analysis of the contents of the bottle showed that it consisted essentially of small proportions of volatile oils including oil of peppermint, oil of eucalyptus, oil of sassafras, oil of lavender, and turpentine, incorporated in a fixed oil and colored green. Analysis of the contents of the tin box showed that it was a semi-solid containing small proportions of volatile oils, including oil of eucalyptus and oil of peppermint, in a minute amount of ammonium alum incorporated in a petrolatum base. The article was alleged to be misbranded because of false and misleading statements in its labeling which represented and suggested that it would be efficacious in the cure, mitigation, treatment, or prevention of hay fever, rose fever, sinus disease infection of the lungs or other area, head colds, cuts, burns, dark circles under the eyes, sunken cheeks, sallow complexion, tuberculosis of the throat and bones, large red blotches on the legs, tuberculous blotches, difficult breathing, daily elevation of temperature, lost strength, lost weight, pulmonary tuberculosis, and sinus infections; that it would be efficacious to destroy tubercle bacilli, and to cause the diseased tissue to separate from the healthy tissue so that it could be coughed up and cause the lung to heal; and that it would restore action of nasal cilia to a normal and healthy condition and lessen the chances of complicating hay fever with bronchial asthma.

All products were alleged to be misbranded further in that the name "Sinu-Vita" created the misleading impression that the articles were effective treatments for sinus diseases. Certain of the products were alleged to be misbranded further because the accompanying labeling contained false and misleading claims regarding other products, because the labels failed to bear a statement of the quantity of the contents, and because they failed to bear a statement of the common or usual name of each active ingredient, and the name and place of business of the manufacturer, packer, or distributor.

On May 23, 1944, the defendant having entered a plea of nolo contendere, the court imposed a fine of $25 on each of the 4 counts.

1276. Misbranding of "For Blood and Kidneys" medicine. U. S. v. Charles Scheuerman (C. Scheuerman). Plea of guilty. Fine, $100. (F. D. C. No. 11333. Sample No. 48310–F.)

On February 7, 1944, the United States attorney for the Southern District of Ohio filed an information against Charles Scheuerman, trading as C. Scheuerman, Cincinnati, Ohio, alleging shipment of a quantity of a liver, blood, and kidney remedy on or about May 4, 1943, from the State of Ohio into the State of Kentucky. The article was labeled in part: (Bottle) "For Blood and Kidneys * * * C.

Scheuerman"; (circular) "Vegetable Liver Medicine * * * Blood Remedy * * * For Blood and Kidneys."

Analysis of a sample showed that the article was an aqueous solution of plant extractives containing, chiefly, aloe and emodin-bearing drugs.

The article was alleged to be misbranded because of false and misleading statements in its labeling which represented and suggested that it would be efficacious in the cure, mitigation, treatment, or prevention of diseased conditions of the blood and kidneys in general, all diseases of the liver, stomach, bowels, skin, and blood, rheumatism, lumbago, stiffness and soreness of the joints, soreness of the muscles, palpitation of the heart, dizziness, numbness of the limbs, sickness at the stomach, cold hands and feet, bad taste in the mouth, flashes of heat, yellow skin, loss of appetite, sick headache, irregularities of the bowels, diarrhea, dysentery, flux, catarrh, debility, shortness of breath, stagnation of blood, bad circulation, scrofulous sores, tetter, old sores, and acrid humors in the blood; and that it would be efficacious to start the bile from the liver and remove it from the stomach. It was alleged to be further misbranded in that it failed to bear a label containing an accurate statement of the quantity of the contents and the common or usual name of each active ingredient.

On February 29, 1944, the defendant entered a plea of guilty and was sentenced to pay a fine of $100.

1277. Misbranding of Detoxyl Tablets. U. S. v. 12 Packages of Detoxyl Tablets, and a number of booklets and leaflets. Default decree of condemnation and destruction. (F. D. C. No. 11986. Sample No. 67412–F.)

On March 10, 1944, the United States attorney for the Northern District of Ohio filed a libel against 12 packages of Detoxyl Tablets and a number of booklets and leaflets entitled "Autopathic Detoxyl Treatment," "Autopathic Instructions," and "Detoxication, Elimination Nutrition, Why Detoxyl," at Cleveland, Ohio, alleging that the tablets and the booklets and leaflets had been shipped on or about the last week in January 1944, by E. R. Moras, M. D., Highland Park, Ill.; and charging that the tablets were misbranded.

Examination disclosed that the tablets consisted essentially of sodium citrate, calcium glycerophosphate, calcium carbonate, and a small amount of talc.

The tablets were alleged to be misbranded because of false and misleading statements in the booklets and leaflets which represented, suggested, and implied that the article would be effective in the treatment of arthritis, asthma, abscessed tooth, acidosis, anemia, abscess of the appendix, appendicitis, bowels, blood pressure, biliousness, adenoids, Bright's disease, blood poisoning, bronchitis, change of life, constipation, consumption, congestion of the lungs, flu, head, heart, hemorrhoids, milk-leg, nephritis, nose peritonitis, stomach trouble, spasm, sex organs, stone in kidney, St. Vitus's dance, toxins, uterine tumor, weak bladder, colds, colitis, chicken pox, chronic ailments, cystitis, catarrh, diarrhea, diphtheria, diabetes, defense in epidemics, eczema, ear abscess, epilepsy, fevers in adults and children, general debility, gastritis, gall-bladder trouble, headaches and many other aches, hemorrhages, hay fever, high blood pressure, ill-nourished people, indigestion, influenza, inflammation of the bladder, infantile paralysis, liver complaints, malnutrition, measles, any illness, neuritis, nervous ailments and breakdown, nausea and vomiting of pregnancy, neuralgias, over-acidity, obesity, over-weight, over-fat people, piles, pellagra, pneumonia, pleurisy, detoxication and elimination, rheumatic fever, rheumatism, sciatica, skin disease, stroke, septicemia, scarlet fever, sinus troubles, typhoid fever, tonsilitis, tuberculosis, underweight, ulcers of the stomach, whooping cough, arteriosclerosis, hardening of the arteries, and advancing old age.

The article was alleged to be further misbranded because of false and misleading statements appearing on the carton which represented and suggested that the product was effective as an aid to detoxication, elimination, and nutrition; and in that it was fabricated from two or more ingredients and its label failed to bear the common or usual name of each active ingredient.

On June 19, 1944, no claimant having appeared, judgment of condemnation was entered and the tablets and aforesaid printed matter were ordered destroyed.

1278. Misbranding of Paracelsus. U. S. v. 9 Cans, 2 Cans, and 9 Cans of Paracelsus. Default decree of destruction. (F. D. C. No. 11825. Sample Nos. 3786–F, 3787–F.)

On or about February 18, 1944, the United States attorney for the Western District of Missouri filed a libel against 9 cans, each containing 160 grams, 2 cans, each containing 320 grams, and 9 cans, each containing 600 grams, of Paracelsus at Kansas City, Mo., alleging that the article had been shipped on or about November 29 and December 16, 1943, from Cleveland, Ohio, by the American Biochemical Corporation; and charging that it was misbranded.

Analysis of samples disclosed that the article was a mixture of inorganic salts, principally sodium phosphate, calcium lactate, potassium chloride, table salt, magnesium sulfate, sodium bicarbonate, and lesser quantities of other chemical salts.

The article was alleged to be misbranded because of false and misleading statements on the can label and in the accompanying circulars entitled "Paracelsus Food and Health," "Here's What They Say About Paracelsus," "Paracelsus Its Aim and Object," and "The Active Life of These Two," which represented and suggested that the article was of substantial value as a dietary supplement in respect to the mineral elements, calcium, chlorine, iron, iodine, lithium, manganese, magnesium, phosphorus, potassium, sodium, sulfur, silicon, and copper, and that these elements are not ordinarily present in adequate amounts in the average diet; that the article was a body builder and a tonic; that it would correct all disorders arising from dietary deficiencies; that it was effective in the treatment of arthritis, rheumatism, neuritis, coughs, asthma, and general debility; that it was of value in improving the functions of all body organs; that it would provide vigor and vitality, aid digestion, and purify blood; and that it was a combination of inorganic minerals in their most assimilable form that would supply minerals necessary in normal nutrition in most desirable portions.

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

On April 20, 1944, no claimant having appeared, judgment was entered ordering that the product be destroyed.

1279. Misbranding of Food Ferrin, Kaba, and Lacto-Dextrin. U. S. v. 13 Jars of Food Ferrin, 5 Cartons of Kaba, and 70 Packages of Lacto-Dextrin. Default decrees of condemnation and destruction. (F. D. C. No. 12107. Sample Nos. 39182–F to 39184–F, incl.)

On April 13, 1944, the United States attorney for the Northern District of Illinois filed libels against the above-mentioned products at Chicago, Ill., alleging that the articles had been shipped by the Battle Creek Food Co. between the approximate dates of July 22, 1943, and January 31, 1944, from Battle Creek, Mich.

Examination disclosed that the Food Ferrin yielded 1.34 percent of ash (total mineral matter); and that 1 tablespoonful of the preparation weighed approximately 16 grams and contained approximately 16 milligrams of iron. The article was alleged to be misbranded in that a leaflet entitled "Do You Need Iron?", which accompanied the article, contained the following statements: "did you know that 10,000,000 of your red blood cells die every second. If they aren't replaced by fresh, new red blood cells, you may soon grow pale, listless, lacking energy and endurance and become an easy prey to disease," which statements were misleading since the labeling of the article failed to reveal the material fact that the body normally replaces red blood cells that die, so that the death of the cells does not ordinarily result in paleness, listlessness, lack of energy and endurance, and increased susceptibility to disease.

The Food Ferrin was alleged to be misbranded further because of false and misleading statements in accompanying leaflets entitled "Do You Need Iron?", "No More 'Menu Monotony'," and "Plan Your Meals for Health," and in an accompanying booklet entitled "Healthful Living," which represented and implied that the article, when taken in accordance with the directions on the package, would supply sufficient iron to constitute an adequate treatment in iron-deficiency conditions; that ordinary foodstuffs do not supply the body with ample supplies of iron; that the article would round out the diet and encourage the growth of new, vigorous, red blood; that it was a remedy for a fagged-out condition and for absence of appetite; that it was rich in organic minerals other than iron, and that it would supply significant amounts of minerals other than iron; that it would constitute an adequate agent for nutritional anemia and increase the hemoglobin content of the blood; and that its iron content was more readily available than iron in common foods. The article would not accomplish the results claimed, suggested, and implied in the labeling; ordinary foodstuffs provide ample supplies of iron; and the iron content of the article was not more readily available than is iron in common food.

Examination disclosed that the Kaba consisted essentially of a gum, milk sugar, starch, yeast, and salt. The article was alleged to be misbranded because of false and misleading statements in accompanying leaflets entitled "Kaba," and "You Too Can Reduce," which represented and implied that use of the article would cause regularity of the bowels, help to re-educate the constipated colon, serve as a treatment for colitis, keep one feeling "in the pink," remedy a furry tongue,

foul breath, "loggy" head, or a tight, "unnatural feeling" in the abdomen, and cause reduction in weight. The article would not be effective to produce the results claimed.

Examination disclosed that the Lacto-Dextrin consisted essentially of milk sugar (approximately 80.5 percent) and dextrin (approximately 18.6 percent). The article was alleged to be misbranded because of false and misleading statements on the label and in accompanying leaflets entitled "Tired?," "Healthful Living," and "Diet Suggestions for High Blood Pressure," which represented and implied that the article would promote the growth of protective organisms, prevent or relieve tiredness, a feeling of sluggishness, being under par, coated tongue, foul breath, headaches, fatigue, a tired feeling, listlessness, excessive intestinal putrefaction, malaise, pains, etc.; and that it would eliminate toxins or keep one free from toxic symptoms, remedy inability to concentrate, and be effective in the treatment of high blood pressure. The article would not be effective to produce the results claimed and implied in the labeling.

The articles were also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

On June 7, 1944, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

1280. Misbranding of Vin-Kre-Ol and Ba-Bow Corrective. U. S. v. 49 Bottles of Vin-Kre-Ol and 1,575 Bottles of Ba-Bow Corrective. Consent decree of condemnation. Products ordered released under bond to be relabeled. (F. D. C. No. 12320. Sample Nos. 62468–F, 62469–F, 72143–F, 72144–F.)

On or about May 5, 1944, the United States attorney for the Eastern District of Arkansas filed a libel against the above-mentioned products at Blytheville, Ark., alleging that they had been shipped between the approximate dates of July 9, 1943, and March 24, 1944, by Allan and Co., Inc., from St. Louis, Mo.; and charging that they were misbranded.

Analysis of the Vin-Kre-Ol showed that it consisted essentially of small proportions of compounds of calcium, iron, manganese, phosphorus, quinine, strychnine, benzaldehyde, and guaiacol, and sugar, alcohol, and water. The article was alleged to be misbranded because of false and misleading statements in the labeling which represented and suggested that it was effective as a palatable medicine and food for use in general debility or run-down conditions resulting from poor diet or nervous strain; and that it was effective for those recovering from illness or operations, and was an aid to natural recovery.

Analysis of the Ba-Bow Corrective showed that it consisted essentially of compounds of bismuth and zinc, salol, volatile oils including oil of anise and methyl salicylate, gum, alcohol, and water, colored with a pink dye. The article was alleged to be misbranded because of the false and misleading statements in its labeling which represented and suggested that it was effective in the treatment or prevention of heartburn due to hyperacidity; and that it was a corrective, a baby bowel corrective, and was effective in such complaints of the stomach and bowels as the gastric fermentation and diarrhea caused by colitis, summer complaint, and food upsets.

On June 14, 1944, the Benz Medicine Co., Blytheville, Ark., having admitted the allegations of the libel, judgment of condemnation was entered and the articles were ordered released under bond to be relabeled under the supervision of the Food and Drug Administration.

1281. Misbranding of grape juice and pomegranate juice. U. S. v. 28 Dozen Quarts and 100 Dozen Pints of Assorted Grape Juice and Pomegranate Juice. Consent decree of condemnation. Products ordered released under bond. (F. D. C. No. 11544. Sample Nos. 55526–F, 55527–F.)

On January 19, 1944, the United States attorney for the Western District of Washington filed a libel against the above-mentioned articles at Seattle, Wash., alleging that they had been shipped on or about November 17, 1943, from Los Angeles, Calif., by Empire Freight; and charging that they were misbranded. The articles were labeled in part: "Queen Isabella Brand * * * Utt Juice Company,—Tustin, Calif."

Examination of samples indicated that the articles consisted of white grape juice and pomegranate juice.

The articles were alleged to be misbranded in that the statements on their labels, "Fruit Juices are especially high in vital blood minerals and organic acids necessary to correct and maintain normal blood alkalinity and food assimilation," were false and misleading since the articles were not especially high in vital blood minerals and organic acids necessary to correct and maintain normal blood alkalinity and food assimilation.

The articles were also alleged to be misbranded under the provisions of the law applicable to foods, as reported in the notices of judgment on foods.

On February 11, 1944, A. Magnano & Sons, Seattle, Wash., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the products were ordered released under bond to be brought into compliance with the law.

1282. Misbranding of Ivita High Potency Capsules, B Family Tablets, and StafTabs Calcium and Phosphorus Tablets. U. S. v. 5 Packages of Ivita High Potency Capsules, 77 Packages of B Family Tablets, and 46 Packages of StafTabs Calcium and Phosphorus Tablets. Default decrees of condemnation and destruction. (F. D. C. No. 11631. Sample Nos. 38678–F, 38681–F, 38683–F.)

On January 26, 1944, the United States attorney for the Northern District of Illinois filed libels against the above-named products at Chicago, Ill., alleging that they had been shipped between the approximate dates of October 8, 1943, and January 10, 1944, by Modern Products, Inc., from Milwaukee, Wis.; and charging that they were misbranded.

Analysis of the Ivita High Potency Capsules showed that they contained vitamin A. The article was alleged to be misbranded because of false and misleading statements in an accompanying circular entitled "Vitamin A," which represented and implied that the administration of vitamin A would be effective in overcoming flash-blindness during night driving, and in the prevention of infections of the body.

Examination of the B Family Tablets showed that the article contained yeast, thiamine, and riboflavin. It was alleged to be misbranded because of false and misleading statements in the accompanying circulars entitled "Your Diet and Your Nerves," and "Laugh at Your Former Self," which represented and implied that the article would be effective in the prevention or cure of nerve upset, intestinal disorders, pellagra and associated symptoms, gray hair, "that tired feeling," lack of appetite, mental depression, muscular cramps and aches, unhealthy skin, eyes, and hair, nervousness, bickering, irritability, "the jitters," aches and pains, lack of energy in children, skin disease in chicks, loss of weight in pigeons, lack of growth in rats, and nervous disease and disturbances of the alimentary tract in rats. The article would not be efficacious for such purposes.

Examination of the StafTabs showed that the article consisted essentially of calcium, phosphorus, vitamin D, sugars, salt, and a mint flavor. The article was alleged to be misbranded in that certain statements in an accompanying circular entitled "Calcium in Human Nutrition" were false and misleading since they represented and implied that calcium would be efficacious to bring about a strong and true heartbeat, preserve the muscular strength of the body, protect the nerves from irritation, aid clot formation of blood, and promote growth, whereas calcium would not be efficacious for such purposes.

The articles were also alleged to be misbranded under the provisions of the law applicable to foods, as reported in the notices of judgment on foods.

On March 9, 1944, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

1283. Misbranding of Vita-Pure B-Complex Vitamins. U. S. v. 672 Cartons of Vita-Pure B-Complex Vitamins. Default decree of forfeiture and destruction. (F. D. C. No. 11737. Sample No. 47858–F.)

On February 3, 1944, the United States attorney for the Western District of Arkansas filed a libel against 672 cartons, each containing 10 tablets, of the above-named article at El Dorado, Ark., alleging that the article had been shipped on or about March 29, 1943, from Oklahoma City, Okla., by the Roisman Products Co.; and charging that it was misbranded.

Examination disclosed that the article contained 358 micrograms of riboflavin and not more than 166 U. S. P. units of thiamine chloride (B_1) per tablet.

The article was alleged to be misbranded because of false and misleading statements appearing in its labeling which represented and suggested that it would be efficacious to help one keep feeling fit; and that it would be efficacious in the prevention and correction of nervousness, loss of appetite, skin disorders, weakness, neuritis, constipation, fatigue, faulty memory, mental depression, and nutritional anemia.

The article was also alleged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

On April 17, 1944, no claimant having appeared, judgment of forfeiture was entered and the product was ordered destroyed.

1284. Misbranding of Williams Yukol Liniment. U. S. v. 37 Bottles of Yukol and 400 Leaflets. Default decree of condemnation and destruction. (F. D. C. No. 12142. Sample No. 67213–F.)

On April 4, 1944, the United States attorney for the Southern District of Ohio filed a libel against 37 bottles of the above-named product and 400 leaflets entitled "Yukol Daily Relief," at Cincinnati, Ohio, alleging that the drug and the leaflets had been shipped on or about January 19, 1944, by the Newman Products Co., Brooklyn, N. Y.; and charging that the drug was misbranded.

Examination of a sample showed that the drug consisted of a mixture of oils, including not less than 54 percent of a petroleum oil.

The drug was alleged to be misbranded (1) in that the name "Yukol," the statement, "Contains Eucalyptus Oil Thymol Menthol Oil of Camphor Oil of Peppermint," on the bottle label, and the statement, "Australian Oil * * * Eucalyptus Yields tons of Pure Oil * * * health aiding Eucalyptus Oil," and similar statements in an accompanying circular, were false and misleading since a large proportion of the article was petroleum oil; and (2) in that the labeling bore certain statements which were false and misleading since they represented and suggested that the drug was of unusual value in keeping the body sound, sturdy, and safe against infection and many common ailments; that it possessed powerful antiseptic properties; and that it was efficacious in the treatment of asthma, catarrhal conditions, ear trouble, and stiff joints, whereas it was not effective for such purposes, and it was not a powerful antiseptic.

On May 11, 1944, no claimant having appeared, judgment of condemnation was entered and the drug and leaflets were ordered destroyed.

1285. Misbranding of Sul-Ray Collodial Sulphur Mineral Baths. U. S. v. 20¾ Dozen Packages of Sul-Ray Collodial Sulphur Mineral Baths. Default decree of condemnation and destruction. (F. D. C. No. 12015. Sample No. 59537–F.)

On March 14, 1944, the United States attorney for the Eastern District of Michigan filed a libel against 20¾ dozen packages of the above-mentioned product at Detroit, Mich., alleging that the article had been shipped on or about December 7, 1943, by the Sante Chemical Co., New York, N. Y.; and charging that it was misbranded.

Examination showed that the article consisted essentially of sulfur and compounds of sodium with sulfate, borate, carbonate, and phosphate.

The article was alleged to be misbranded in that the name, "Colloidal Sulphur Mineral Baths," was misleading since the article was designated by only one of the ingredients contained in it. It was alleged to be misbranded further in that the statements in its labeling which represented and implied that the benefits to be obtained from a visit to mineral springs could be enjoyed at home through the use of the article, and that sulfur in the bath water is effective in the treatment of muscular aches and pains, rheumatism, arthritis, lumbago, gout, sciatica, itching, and various skin conditions, and to insure deep, refreshing sleep, were false and misleading since the benefits from a visit to a mineral spring do not come solely from bathing in the spring water, but include rest and other forms of treatment, and sulfur in the bath water is not effective in the treatment of the aforementioned disease conditions and symptoms.

On May 1, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1286. Misbranding of Pyrozide Tooth Powder. U. S. v. 124 Packages of Pyrozide Tooth Powder (and 5 other seizure actions against the same product). Default decrees of condemnation. Portion of product ordered delivered to charitable institutions; remainder ordered destroyed. (F. D. C. Nos. 11790, 11959, 12495, 12496, 12633, 12698. Sample Nos. 60707–F, 66223–F, 73311–F, 73316–F, 81770–F, 81771–F.)

Between February 11 and June 19, 1944, the United States attorneys for the Northern District of California and the Southern District of New York filed libels against 226 packages of Pyrozide Tooth Powder at San Francisco, Calif., and 1,006 packages at New York, N. Y., alleging that a portion of the article had been shipped on or about May 10, 1944, by the Block Drug Co., from Jersey City, N. J., and that the remainder of the article had been shipped between the approximate dates of August 11, 1943, and April 6, 1944, by the Web Distributing Co., from Newark, N. J.

Analysis disclosed that the article consisted essentially of calcium carbonate, magnesium carbonate, and small amounts of sassafras, cresol, and soap.

The article was alleged to be misbranded in that certain statements in its labeling regarding its efficacy in the treatment of pyorrhea, gingivitis, trench

mouth, and all other diseases of the oral tissue, were false and misleading since the article would not be efficacious for such purposes.

On December 5, 1944, the libel proceedings against two of the California lots having been removed and consolidated for trial with two of the New York lots, and default having been duly entered thereafter against the claimant for those lots, judgment of condemnation was entered and the product was ordered destroyed. On May 20 and 22, 1944, no claimant having appeared for the remaining two lots, judgments of condemnation were entered and it was ordered that the New York lot be distributed to charitable institutions, and that the California lot be destroyed.

1287. Misbranding of Kojenol. U. S. v. 22 Bottles of Kojenol. Default decree of condemnation and destruction. (F. D. C. No. 12368. Sample No. 49976-F.)

On May 12, 1944, the United States attorney for the Western District of Pennsylvania filed a libel against 22 bottles of the above-mentioned product at Erie, Pa., alleging that the article had been shipped on or about January 11, 1943, and February 21, 1944, by the Johnstone Drug Sales Corporation, from Rochester, N. Y.; and charging that it was misbranded.

Examination showed that the article consisted essentially of oxyquinoline sulfate and water.

The article was alleged to be misbranded in that the statement on its label, "An adjuvant for use under Professional Guidance in the Treatment of Gingivitis and Pyorrhea," was false and misleading since the article would not be effective in the treatment of gingivitis and pyorrhea.

On June 29, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1288. Misbranding of phenobarbital sodium. U. S. v. 188 Ampuls of Phenobarbital Sodium (and 3 other seizure actions against the same product). Default decrees of condemnation and destruction. (F. D. C. Nos. 11641, 11651, 11702, 11740. Sample Nos. 35563-F, 51275-F, 51452-F, 57236-F, 57261-F.)

Between January 17 and February 3, 1944, the United States attorneys for the District of Massachusetts, the District of New Jersey, and the Eastern District of North Carolina filed libels against the following quantities of the above-named product: 188 ampuls at Worcester, Mass., 101 ampuls at Neptune, N. J., 160 ampuls at Raleigh, N. C., and 6 packages at Boston, Mass. On March 7, 1944, the libel against the Neptune lot was amended to cover the seizure of a total of 195 ampuls of the product at that place. It was alleged in the libels that the article had been shipped between the approximate dates of October 21, 1943, and January 3, 1944, from New York, N. Y., by the Loeser Laboratory, Inc. The article was labeled in part: "No. 410-Ampuls-100 [or "Ten"] Phenobarbital Sodium U. S. P. 2 Grains * * * Loeser Laboratory, Inc., New York, N. Y. Subsidiary of The Wm. S. Merrell Company."

The article was alleged to be misbranded in that the statements in its labeling which represented that the article contained, in each ampul, 2 grains of U. S. P. phenobarbital sodium were false and misleading since the amount of phenobarbital sodium in each ampul was not only materially in excess of that declared, but there was an excessive variation between the quantity present in the individual ampuls.

Between March 6 and 14, 1944, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

1289. Misbranding of bandage compresses. U. S. v. 21,482 Bandage Compresses. Consent decree of condemnation. Product ordered released under bond to be resterilized. (F. D. C. No. 12429. Sample No. 65940-F.)

On May 24, 1944, the United States attorney for the Southern District of New York filed a libel against 21,482 bandage compresses at Tuckahoe, N. Y., alleging that the article had been shipped on or about March 13 and 15, 1944, by the Bay Division, Parke, Davis and Co., from Versailles, Conn.; and charging that it was misbranded.

The article was alleged to be misbranded in that the statement on the label, "Sterilized," was false and misleading as applied to the bandages, which were not sterile but were contaminated with living micro-organisms.

On June 19, 1944, Parke, Davis and Co., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond to be resterilized under the supervision of the Food and Drug Administration.

1290. Misbranding of gauze bandages. U. S. v. 156 Boxes of Gauze Bandages. Decree of condemnation. Product ordered released under bond. (F. D. C. No. 11579. Sample No. 11716–F.)

On January 5, 1944, the United States attorney for the Northern District of California filed a libel against 156 boxes, each containing 72 units, of the above-named product at San Francisco, Calif., alleging that the article had been shipped from New Rochelle, N. Y., on or about October 22, 1943, by the American White Cross Laboratories, Inc.; and charging that it was misbranded. The article was labeled in part: "Sterile Bandage Gauze Compressed."

The article was alleged to be misbranded in that the statement, "Sterile," appearing on its label, was false and misleading since the article was not sterile, but was contaminated with living micro-organisms.

On April 27, 1944, the American White Cross Laboratories, Inc., having appeared as claimant, judgment of condemnation was entered and the product was ordered released under bond for resterilization under the supervision of the Food and Drug Administration.

1291. Misbranding of Stanup Shoulder Brace. U. S. v. 38 Stanup Shoulder Braces. Consent decree of condemnation. Product ordered released under bond to be relabeled. (F. D. C. No. 11817. Sample No. 59536–F.)

On February 15, 1944, the United States attorney for the Eastern District of Michigan filed a libel against 38 Stanup Shoulder Braces at Detroit, Mich., alleging that the article had been shipped between the approximate dates of November 12 and 20, 1943, by the United States Truss Co., Cincinnati, Ohio; and charging that it was misbranded.

Examination showed that the device was a shoulder brace made of strips of cotton webbing, the shoulder straps being adjustable.

It was alleged to be misbranded in that the following statements appearing on the label, "Shoulder Erector and Chest Expander For Men and Women Young and Old Develops the Chest * * * then see how your chest will develop within a short time * * * Health Promoter Deep Breathing Expands Lungs Purifies Blood and Prolongs Life," were false and misleading since such a device would not be effective in developing the chest, expanding the lungs, purifying the blood, prolonging life, or promoting health.

On March 16, 1944, the United States Truss Co., claimant, having admitted the facts in the libel, judgment of condemnation was entered and the product was ordered released under bond to be relabeled under the supervision of the Food and Drug Administration.

1292. Misbranding of Rowles Red Pepper Rub. U. S. v. 85½ Dozen Packages of Rowles Red Pepper Rub. Decree of condemnation. Product ordered released under bond to be relabeled. (F. D. C. No. 11826. Sample No. 60705–F.)

On February 17, 1944, the United States attorney for the Northern District of California filed a libel against 85½ dozen packages of Rowles Red Pepper Rub at San Francisco, Calif., alleging that the article had been shipped by the Anacin Manufacturing Co. on or about March 30, 1943, from Knoxville, Tenn.; and charging that it was misbranded.

Examination disclosed that the article was short-weight.

It was alleged to be misbranded (1) in that the statement in the labeling, "Contents 1¼ Oz.," was false and misleading; and (2) in that the label failed to bear an accurate statement of the quantity of the contents.

On March 31, 1944, the Larned Corporation having appeared as claimant, judgment of condemnation was entered and the product was ordered released under bond to be relabeled under the supervision of the Food and Drug Administration.

DRUGS FOR VETERINARY USE*

1293. Misbranding of Cha Rem. U. S. v. 222 Bottles of Cha Rem. Decree of condemnation. Product ordered released to be relabeled. (F. D. C. No. 12020. Sample No. 62531–F.)

On March 20, 1944, the United States attorney for the Eastern District of Illinois filed a libel against 222 bottles, ranging from 8 ounces to 1 gallon in size, of Cha Rem, at Windsor, Ill., alleging that the article, which had been consigned by the F. B. Chamberlain Co., had been shipped on or about February 1 and March 8, 1944, from St. Louis, Mo.; and charging that it was misbranded.

Examination of the article showed that it consisted essentially of water, sugar, creosote, sodium hydroxide, a laxative plant drug, and a minute amount of arsenic.

*See also Nos. 1259–1261, 1282.

The article was alleged to be misbranded because of false and misleading statements in accompanying circulars entitled "How to Keep Your Chickens Healthy," and "Coccidiosis Kills Millions of Chickens Every Year," regarding its efficacy as a drinking water disinfectant and in the prevention of coccidiosis (both bloody type and chronic), bronchitis and respiratory diseases, range paralysis, bowel trouble, and mycosis, and in the treatment of coccidiosis (bloody type), bronchitis, limber neck, and general bowel disorders.

On April 8, 1944, the F. B. Chamberlain Co., St. Louis, Mo., and Harold Storm, doing business as Storm's Seed and Feed Store, Windsor, Ill., claimants, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released to the claimants, conditioned that it be relabeled and that the circulars be destroyed under the supervision of the Food and Drug Administration.

1294. Misbranding of Economy veterinary products. U. S. v. 40 Bags and 23 Bags of Economy Super-Mineral for Poultry, 4 Bags of Economy Super-Mineral for Sheep, and various quantities of printed matter. Consent decree of condemnation. Printed matter ordered destroyed; products ordered released under bond. (F. D. C. No. 10181. Sample Nos. 37976–F, 37978–F.)

On July 12, 1943, the United States attorney for the Northern District of Indiana filed a libel against 40 25-pound bags and 23 50-pound bags of Economy Super-Mineral for Poultry, and 4 50-pound bags of Economy Super-Mineral for Sheep, 2,000 booklets entitled "The Key to Success Economy Super-Mineral for Poultry," 200 circulars entitled "Economy Super-Mineral for Poultry Feeding Directions," 4,000 booklets entitled "The Key to Success Economy Super-Mineral for Sheep," and 200 circulars entitled "Economy Super Minerals for Sheep General Feeding Directions," at Fort Wayne, Ind. It was alleged that the drugs had been shipped on or about February 23, 1943, by the James J. Doty Co., Ltd., from Shenandoah, Iowa, and that the booklets and circulars had been brought together with the drug to which they referred, and accompanied the articles while they were in interstate commerce.

Analysis of a sample of the Mineral for Poultry showed that it consisted essentially of sodium sulfate, calcium carbonate, sodium bicarbonate, sulfur, plant drugs including tobacco and American wormseed, small amounts of calcium phosphate, sodium thiosulfate, manganese sulfate, iron oxide, charcoal, and an iodide. It contained not more than 0.14 percent of phosphoric anhydride, not more than 0.06 percent of phosphorus, and not more than 0.007 percent of iodine. It was alleged to be misbranded in that certain statements in the labeling were false and misleading since they represented that the article would be efficacious to regulate the digestive organs, act as a tonic for poultry, act as a preventive of coccidiosis, regulate the kidneys and liver, restore the healthy functions of the body, disperse a tumor, rid the system of uric acid, regulate the bowels, prevent gland troubles, and act as a tonic for the blood; that it would be efficacious in the treatment of white diarrhea, blackhead, worms—round, tape, and gape, diphtheritic roup, and chicken pox or sore-head; and that it would build the constitution. The article would not be efficacious for such purposes.

Analysis of a sample of the Mineral for Sheep showed that it consisted essentially of sodium sulfate, calcium carbonate, sulfur, and sodium bicarbonate with small amounts of calcium phosphate, charcoal, iron oxide, manganese sulfate, sodium thiosulfate, an iodide, and plant drugs including tobacco and American wormseed; and that it contained not more than 0.07 percent of phosphorus and not more than 0.007 percent of iodine. It was alleged to be misbranded in that certain statements in the labeling were false and misleading since they represented that the article would be efficacious in the treatment of worms, gastritis, and enteritis in sheep; that it would clean out the digestive tract, regulate the bowels, liver, and kidneys; that it would disperse a tumor, act as an internal antiseptic healing lotion to any injured or ulcerated portion of the digestive tract, restore healthy functions of the body, regulate the bowels, and tone the blood; that it would be efficacious in the treatment of catarrh or snotty nose, bloating, and forage poisoning; and that it would supply the necessary elements for health and reproduction. The article would not be efficacious for such purposes.

On October 22, 1943, the Economy Hog & Cattle Powder Co., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and it was ordered that the booklets and circulars be destroyed, and that the drugs be released under bond for relabeling under the supervision of the Food & Drug Administration.

1295. Misbranding of Sunshine Minerals. U. S. v. 465 Bags of Sunshine Minerals and 1,300 Circulars. Consent decree of condemnation. Product ordered released, conditioned upon destruction of the circulars. (F. D. C. No. 10830. Sample No. 43068–F.)

On or about October 5, 1943, the United States attorney for the District of Oregon filed a libel against 465 100-pound bags of Sunshine Minerals and 1,300 circulars at Portland, Oreg. It was alleged in the libel that the Sunshine Minerals had been shipped from South San Francisco, Calif., on or about September 15, 1943, by the Korinek Laboratories; and charged that it was misbranded.

The article was labeled in part: "Dr. C. J. Korinek's Sunshine * * * Minerals * * * Mineral Compound for Poultry-Cattle-Horses-Hogs-Sheep * * * 100 pounds net contains Iodine requirements * * * Minerals * * * For further feeding directions see circular on Dr. C. J. Korinek's Sunshine Minerals * * * Analysis. Calcium (CA), not less than 30.00% Phosphorus (P), not less than 2.00% Iodine (I), not less than .06% Salt. .00%." Analysis showed that the article had essentially the composition stated on its label.

The article was alleged to be misbranded because of false and misleading statements in the labeling regarding its efficacy to promote maximum growth development in poultry and ability to produce high grade eggs; assure strong, sturdy, uniform development of chicks and pullets; build up body resistance to disorders and diseases affecting poultry; build stronger bones and muscles and digestive and other internal organs; reduce nutritional leg weaknesses, rickets, rubber legs, malformed breastbones, slip tendons, blindness, paralysis, and roup; improve egg quality and shell texture; increase firmness, compactness, and thickness of shells; increase egg production up to 19 percent; improve hatchability and fertility of hatching eggs; prevent perosis; and reduce mortality up to 32 percent.

It was alleged to be misbranded further because of false and misleading representations regarding its efficacy to increase milk production up to 9 percent in cows; keep cows producing profitably for years, thus reducing costly replacements; reduce nutritional abortion, sterility, or non-breeding, retained afterbirth, milk fever, simple garget, red water, and anemia; prevent unthrifty condition, chewing bones, leather, wood, or eating dirt; prevent swollen joints; eliminate goiter, rickets, and various other deformities in calves; reduce scours; assure large, thrifty, well-haired calves; and help cows to develop and drop healthier calves.

The article was alleged to be misbranded further because of false and misleading statements regarding its efficacy to insure large, healthy litters in hogs, and make sows better mothers; prevent hairless pigs, and mothers eating their young soon after birth; prevent milk fever and retained afterbirth in sows; reduce paralysis and thumps (anemia); increase the flow of the sow's milk; increase weight from 10 percent to 20 percent; build strong, sturdy bones; improve breeding conditions in both sows and boars; help sows to farrow; promote a general thriftiness in pigs, and sharpen their appetites; prevent sagged back, weak pasterns, and small bones; and satisfy the unnatural craving which makes hogs root.

It was alleged to be misbranded further because of false and misleading statements regarding its efficacy to increase weight and fleeces from 4 percent to 18 percent in sheep; grow strong, sturdy, well-boned sheep; reduce nutritional abortions, sterility or shy-breeding, retained afterbirth, suspension of the milk of ewes after lambing, heaving pains, blue-bag, anemia (thumps), goiters, and rickets in lambs; improve the general health; increase the milk flow of ewes; prevent stiff diseases in lambs, and dirt- or sand-eating in sheep and lambs; eliminate failure to breed; produce larger, well-haired fox pups; improve pelts greatly; invigorate breeding conditions of both male and female foxes; increase production among rabbits, the size and thrift of litters; prevent the doe eating the young; build up effective resistance from many disorders common to rabbits; keep the hair of dogs in fine condition; give dogs lots of energy and pep; and reduce dog deficiency diseases.

On November 1, 1943, Dr. C. J. Korinek, claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released to the claimant, conditioned that the circulars be destroyed.

1296. Misbranding of Superior Chemicals. U. S. v. 300 Bags of Superior Chemicals. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 11727. Sample No. 60301–F.)

On February 2, 1944, the United States attorney for the District of Nevada filed a libel against 300 bags, each containing 100 pounds, of Superior Chemicals at Reno, Nev., alleging that the article had been shipped on or about July 14, 1943,

from Mt. Olivet, Colo., by the Superior Products Co.; and charging that it was misbranded. The article was labeled in part: "Superior Chemicals * * * [Pictures of horse, sheep, ass, shorthorn, pig, and bull] * * * Sodium Salicylate."

Analysis disclosed that the article contained salt (58.4 percent), calcium carbonate (25.9 percent), small amounts of other mineral substances, charcoal, and turpentine oil; and that it contained no sodium salicylate.

The article was alleged to be misbranded because of false and misleading statements appearing in circular letters accompanying it which represented and suggested that the article was of value in the prevention and treatment of diseases of livestock due to insect or parasitic infestations, and also in the treatment of scours, mange, worms, and boils, retention of afterbirth, kidney trouble, pneumonia, abortion, ringworm, lumpy jaw, and sleeping sickness. The article was alleged to be further misbranded in that the statement on the label, "Active Ingredients * * * Sodium Salicylate," was false and misleading since the article contained no sodium salicylate.

On May 20, 1944, the Cremer-Erickson Co., Reno, Nev., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond to be brought into compliance with the law, under the supervision of the Federal Security Agency.

1297. Misbranding of Bob Armstrong's Distemper Remedy. U. S. v. 12 Boxes of Bob Armstrong's Distemper Remedy. Default decree of condemnation and destruction. (F. D. C. No. 11970. Sample No. 35678–F.)

On March 11, 1944, the United States attorney for the Western District of South Carolina filed a libel against 12 boxes, each containing 4 capsules, of the above-named product at Laurens, S. C., alleging that the article had been shipped on or about October 10, 1943, from Fitzgerald, Ga., by R. K. Armstrong; and charging that it was misbranded.

Examination of a sample of the article disclosed that the capsules contained large and varying amounts of arsenic, opium, and ginger.

The article was alleged to be misbranded (1) in that the name "Distemper Remedy," and the statements appearing in the circular contained in the package, "Very often a sick dog will not eat from a man, but will eat when given food by a woman. A sick dog needs careful nursing. At the very first symptoms give a capsule, for if caught early often three applications are enough," were false and misleading since the article would be of no value whatever in the treatment of the disease of dogs known as distemper; (2) in that its label failed to bear an accurate statement of the quantity of contents; and (3) in that it was fabricated from two or more ingredients and its label failed to bear the common or usual name of each active ingredient, or the quantity of arsenic contained therein.

On April 11, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1298. Misbranding of Munchy Dog Food. U. S. v. 224 Bags, 72 Bags, and 164 Bags of Dog Food. Default decree of condemnation and destruction. (F. D. C. No. 11845. Sample Nos. 49863–F, 49864–F.)

On February 18, 1944, the United States attorney for the Western District of Pennsylvania filed a libel against 224 5-pound bags and 72 2-pound bags of dog food (meal), and 164 2-pound bags of dog food (pellets), at Erie, Pa., alleging that the article had been shipped on or about December 28, 1943, by the Park & Pollard Co., Inc., from Buffalo, N. Y.; and charging that it was misbranded.

The article was labeled in part: "Meat Laden Munchy Dog Food (Meal)," or "Munchy Pellets * * * Munchy Dog Food." On the labels the ingredients of the product were declared as: "Meat Scraps, Flaked Corn and Wheat Cereal, Dried Yeast, Dried Skim Milk, Soybean Meal Flakes, Ground Malt, Fish Meal, Kelp, Wheat Germ Oil, Calcium Carbonate, Bone Meal, Manganese Sulphate, Fortified Cod Liver Oil. Guaranteed Analysis Protein (at least) 26%." Examination revealed that the product had essentially the qualitative composition stated on its label; that the only meat constituent of the product was meat and bone scraps, which were present to the extent of less than 10 percent; and that the product contained 12 percent less than the 26 percent of protein declared.

The article was alleged to be misbranded in that the statements on the label, "Aids in Maintaining Good Health Growth A Full, Rich Coat Good Bone Formation Sound Teeth Sweet Breath Healthy Skin Resistance to Colds and Distemper * * * Safeguards Against Rickets, Black Tongue & Other Diseases Due to Nutritional Deficiencies," were false and misleading since the article would not accomplish the results suggested and implied.

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

On April 12, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF OMISSION OF, OR UNSATISFACTORY, INGREDIENTS STATEMENTS*

1299. Misbranding of Magic Fire Liniment. U. S. v. George Foster, Inc., and George Foster. Pleas of guilty. Fines: $100 against corporate defendant, $500 against individual defendant. (F. D. C. No. 10589. Sample No. 8692–F.)

On December 27, 1943, the United States attorney for the District of Minnesota filed an information against George Foster, Inc., St. Paul, Minn., and George Foster, president of the corporation, alleging shipment from the State of Minnesota into the State of Wisconsin, on or about March 12, 1943, of a quantity of the above-named product. The article was labeled in part: (Bottles) "Magic Fire Red Hot Wonder Liniment."

The article was alleged to be misbranded in that it was not sold under a name recognized in an official compendium, and it was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient.

It was also alleged in the information that another article, Egg-O-Save, was misbranded under the provisions of the law applicable to foods, as reported in the notices of judgment on foods.

On February 19, 1944, pleas of guilty having been entered by and on behalf of the defendants, the court imposed a fine of $100 against the corporation and a fine of $500 against the individual.

1300. Misbranding of an unlabeled drug product. U. S. v. 768 Packages of an Unlabeled Drug Product. Decree of condemnation. Product ordered released under bond. (F. D. C. No. 10952. Sample No. 3924–F.)

On or about October 20, 1943, the United States attorney for the Western District of Missouri filed a libel against 768 packages of an unlabeled drug product at Kansas City, Mo., alleging that the article had been shipped on or about September 14, 1943, from Detroit, Mich., by the Nu-Basic Products Co.

Analysis of a sample showed that the article consisted essentially of unsaponifiable oil containing small proportions of carbolic acid, sulfanilamide, a saponifiable oil, and water.

The article was alleged to be misbranded in that it did not bear a label containing the name and place of business of the manufacturer or distributor, nor an accurate statement of the quantity of contents in terms of weight or measure; and in that it was fabricated from two or more ingredients and was not labeled to show the common or usual names of the active ingredients.

On October 26, 1943, the Nu-Basic Products Co. having appeared as claimant, judgment of condemnation was entered and the product was ordered released under bond for labeling in compliance with the law, under the supervision of the Food and Drug Administration.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 1251 TO 1300

PRODUCTS

*See also Nos. 1258, 1260, 1261, 1274–1277, 1297.

[1] Prosecution contested.

SHIPPERS AND MANUFACTURERS

[1] Prosecution contested.
[2] Seizure contested. Contains court opinions.

[2] Seizure contested. Contains court opinions.

U. S. GOVERNMENT PRINTING OFFICE: 1945

D. D. N. J., F. D. C. 1301-1350 Issued November 1945

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

1301—1350

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

WATSON B. MILLER, *Acting Administrator, Federal Security Agency.*
WASHINGTON, D. C., *July 19, 1945.*

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DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

1301. Misbranding of phenobarbital sodium ampuls and procaine hydrochloride ampuls. U. S. v. Loeser Laboratory, Inc., and Karl B. Rosen. Pleas of guilty. Corporate defendant fined $1,400; imposition of sentence suspended against individual defendant, who was placed on probation for 30 days. (F. D. C. No. 12556. Sample Nos. 50011-F, 50257-F, 51778-F, 51779-F, 65986-F, 65987-F, 77807-F.)

On November 6, 1944, the United States attorney for the Southern District of New York filed an information against the Loeser Laboratory, Inc., New York, N. Y., and Karl B. Rosen, secretary of the corporation, alleging shipment of a quantity of phenobarbital sodium ampuls from the State of New York into the State of New Jersey on or about December 2, 1943, and shipment of quantities of procaine hydrochloride ampuls from the State of New York into the States of New Jersey, Pennsylvania, and New Hampshire between the approximate dates of June 18 and December 13, 1943. The articles were labeled in part: "Phenobarbital Sodium [or "Procaine Hydrochloride"]

*For presence of a habit-forming narcotic without warning statement, see No. 1306; presence of an uncertified coal-tar color, No. 1345; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 1309, 1324, 1325; failure to bear an accurate statement of the quantity of the contents, Nos. 1306, 1309, 1324, 1326, 1336, 1337; omission of, or unsatisfactory, ingredients statements, Nos. 1307, 1309, 1314, 1326, 1338, 1341; inconspicuousness of required label information, Nos. 1328, 1334; deceptive packaging, No. 1337; cosmetics, subject to the drug provisions of the Act, Nos. 1335, 1337.

* * * Loeser Laboratory, Inc., New York, N. Y. Subsidiary Of The Wm. S. Merrell Company."

The phenobarbital sodium was alleged to be misbranded in that the statements on its labels, "Phenobarbital Sodium U.S.P. 2 Grains * * * Each ampul contains Phenobarbital Sodium, U.S.P. 0.13 Gm. (2 grs.)," and "Phenobarbital Sodium U.S.P. * * * 2 Grains," were false and misleading since the article contained phenobarbital sodium in amounts varying from 2.04 grains (0.1324 gram) to 2.78 grains (0.1800 gram).

The procaine hydrochloride was alleged to be misbranded in that the statements on its labels, "Procaine Hydrochloride, U.S.P. 50 mg. [or "100 mg.," "120 mg.," "150 mg.," or "200 mg."]," were false and misleading since the article contained the following amounts of procaine hydrochloride: 66.4 mg. to 106.3 mg. in the 50-mg. lot; 100.7 mg. to 157.6 mg. in the 100-mg. lot; 74.4 mg. to 104.8 mg. in the 120-mg. lot; 49.3 mg. to 147.4 mg. in a portion of the 150-mg. lot, and 166.3 mg. to 235 mg. in the remainder of the 150-mg. lot; and 224.8 mg. to 284.5 mg. in the 200-mg. lot.

The procaine hydrochloride was alleged to be misbranded further in that, by reason of the variance of the contents of the ampuls from the amounts declared on the labels, the article would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, and suggested in its labeling, i.e., "For spinal anesthesia by admixture with spinal fluid * * * To be used only by or on the prescription of a physician."

On November 10, 1944, pleas of guilty were entered on behalf of the defendants, and on November 13, 1944, the corporate defendant was fined $200 on each of the 7 counts, a total fine of $1,400; imposition of sentence against the individual defendant was suspended, and he was placed on probation for 30 days.

1302. Adulteration of Eye-Gyrol and misbranding of Stero-Uteroids. U. S. v. Lloyd M. Curts and Charles D. Folse (Curts-Folse Laboratories). Pleas of guilty. Fine, $200. (F. D. C. No. 7722. Sample Nos. 73167-E, 73170-E.)

On November 7, 1942, the United States attorney for the District of Kansas filed an information against Lloyd M. Curts and Charles D. Folse, copartners trading as the Curts-Folse Laboratories, Kansas City, Kans., alleging shipment of a quantity of the above-named products from the State of Kansas into the State of Missouri on or about August 4 and December 10, 1941.

The Eye-Gyrol was alleged to be adulterated in that its strength differed from that which it purported or was represented to possess, since it purported and was represented to contain 12½ percent of argyrol, whereas it contained argyrol in amounts varying from 4.35 percent to 8.30 percent.

Analysis of the Stero-Uteroids disclosed that the article consisted essentially of small proportions of zinc sulfate, plant material including alkaloid-bearing drugs, and a trace of iodine incorporated in a base of ichthyol and wool fat. It was alleged to be misbranded (1) in that its name, "Stero-Uteroids," the fact that it was packaged in a collapsible metal tube with key, and the directions on the labels, "Apply with catheter under aseptic conditions," suggested the introduction of the article into the uterus by means of a catheter, whereas the article, when introduced into the uterus, would be dangerous to health; and (2) in that the statements, "Stero-Uteroids * * * Directions: Apply with catheter under aseptic conditions. For administration by physician only," borne on the labels, were false and misleading since they represented and suggested that the article was a safe medicament for introduction into the uterus under aseptic conditions by a physician, whereas the article was not a safe medicament for introduction into the uterus under aseptic conditions, or any condition, by a physician or other person.

On April 3, 1944, the defendants having entered pleas of guilty, the court imposed a fine of $100 on each of 2 counts, a total fine of $200.

1303. Adulteration and misbranding of Rx 56 Special Prescription Compound for Alcoholism. U. S. v. Mrs. Ethel G. Jeffery (Mar-Dor Laboratories). Plea of guilty. Imposition of sentence suspended, and defendant placed on probation for 2 years, conditioned upon the discontinuance of the sale of medical articles. (F. D. C. No. 12552. Sample No. 8174-F.)

On September 11, 1944, the United States attorney for the District of Minnesota filed an information against Ethel G. Jeffery, trading as the Mar-Dor Laboratories, Minneapolis, Minn., alleging shipment of a quantity of the above-named product on or about August 21, 1943, from the State of Minnesota into the State of Wisconsin.

Analysis of a sample disclosed that the article was in the form of capsules, each of which contained 0.21 gram of potassium bromide, 6.4 milligrams of benzedrine sulfate, and thiamine chloride.

The article was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess, since it purported and was represented to contain 0.4 gram of potassium bromide in each capsule, whereas it contained not more than 0.21 gram of potassium bromide in each capsule.

The article was alleged to be misbranded (1) because of false and misleading statements on its label and in the accompanying leaflet and circular entitled, "Instructions for Rx 56 Treatment for Alcoholism," and "'Rx56' Special Compound An Aid to Drinkers," respectively, regarding its efficacy in the cure, mitigation, treatment, and prevention of alcoholism; (2) in that the statement on the label, "Potassium Bromide Grams 0.4 * * * Each Capsule," was false and misleading; and (3) in that the article, because of the presence of 6.4 milligrams of benzedrine sulfate, would be dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the aforesaid circular, i.e., "This treatment for the average patient using 1 to 3 capsules a day."

On October 14, 1944, the defendant having entered a plea of guilty, the court suspended imposition of sentence, and placed her on probation for a period of 2 years, conditioned that she refrain from engaging in the sale of medical articles of any kind.

1304. Misbranding of Lambert's Tablets and Lambert's Powders. U. S. v. Claude M. Stanley (Stanley Drug Co.). Plea of guilty. Fine, $50 on first count; sentence suspended on second count, and defendant placed on 1 year's probation. (F. D. C. No. 11410. Sample Nos. 47507-F, 47508-F.)

On June 12, 1944, the United States attorney for the District of Minnesota filed an information against Claude M. Stanley, trading as the Stanley Drug Co., at Minneapolis, Minn., alleging shipment on or about July 23, 1943, from the State of Minnesota into the State of Iowa of a quantity of the above-named articles.

Analysis showed that the tablets each contained 2½ grains of aspirin, 1¼ grains of acetanilid, and 1¼ grains of salol, and that the powders each contained 5.74 grains of aspirin, 2.44 grains of acetanilid, and 2.81 grains of salol.

The articles were alleged to be misbranded (1) in that they would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, and suggested in the labeling, (tablets) "Directions Take * * * 2 tablets with a glass of water. Repeat dose every 3 or 4 hours, preferably before eating and at bedtime," and (powders) "Directions Adult Dose—The contents of one powder, with a large glass of water, taken before meals, three times a day," since they contained approximately 1¼ grains of acetanilid per tablet, and approximately 2½ grains of acetanilid per powder, and their use, as prescribed, recommended, and suggested in the directions, would result in the administration of excessive amounts of acetanilid; (2) in that the labeling failed to bear warnings that frequent or continuous use might cause serious blood disturbances, anemia, collapse, or dependence on the article; and the labeling of the tablets failed to reveal that they should not be given to children; (3) in that the statements in the labeling, (tablets) "For relief of * * * discomfort in * * * muscular aches and pains, neuralgia, common head colds," and (powders) "For Relief Of Simple Colds, * * * Muscular Aches, Body Pains, Caused By Exposure," were false and misleading since the articles would not be efficacious for such purposes; and (4) in that the statements on the box containing the powders, "Acetylsalicylic Acid Grs. 5 * * * Phenyl Salicylate Grs. 2.5," were false and misleading since the article contained materially more than 5 grains of acetylsalicylic acid, and materially more than 2.5 grains of phenyl salicylate.

On December 1, 1944, the defendant having entered a plea of guilty, the court imposed a fine of $50 on the first count of the information, suspended imposition of sentence on the second count, and placed the defendant on probation for the period of 1 year.

1305. Misbranding of Rudy's Pile Suppository. U. S. v. 36 Packages of Rudy's Pile Suppository. Default decree of condemnation and destruction. (F. D. C. No. 12361. Sample No. 79374-F.)

On May 11, 1944, the United States attorney for the Eastern District of Virginia filed a libel against 36 packages of the above-mentioned product at Norfolk, Va., alleging that the article had been shipped on or about February 14, 1944, by the Martin Rudy Estate, from Lancaster, Pa.

Examination of samples showed that the article consisted essentially of lead carbonate 0.25 grain, tannic acid, creosote, and iodoform in a suppository base.

The article was alleged to be misbranded (1) in that the statement in the labeling, "Tends to relieve the discomforts of Piles (Bleeding * * * Protruding)," was false and misleading since the article would not constitute a safe and effective treatment for the discomfort of bleeding and protruding piles; (2) in that its labeling failed to bear adequate warnings against its use in the case of bleeding piles; and (3) in that it was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the label.

On July 14, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

1306. Adulteration and misbranding of Dr. Hubbels Formula for Dental Hygiene. U. S. v. Hubbel Products Corporation. Plea of guilty. Fine, $50. (F. D. C. No. 12597. Sample No. 52281-F.)

On November 6, 1944, the United States attorney for the District of Massachusetts filed an information against the Hubbel Products Corporation, Boston, Mass., alleging shipment of a quantity of the above-named product from the State of Massachusetts into the State of Maine, on or about March 11, 1944.

The article was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess, since it was represented as containing 8 grains of chloral hydrate to the fluid ounce, whereas it contained approximately 14 grains of chloral hydrate to the fluid ounce.

It was alleged to be misbranded (1) in that the statement on its label, "Chloral Hydrate 8 grs. to Fluid Oz.," was false and misleading; (2) in that its label bore no statement of the quantity of the contents; (3) in that its labeling bore no directions for use; and (4) in that it was a drug for use by man, and it contained chloral hydrate, a derivative of chloral, which derivative, by regulations, has been designated as habit-forming, but the label of the article did not bear the name and quantity or proportion of the derivative and, in juxtaposition therewith, the statement "Warning—May be habit-forming."

On December 27, 1944, a plea of guilty having been entered on behalf of the corporation, the court imposed a fine of $25 on each of 2 counts, a total fine of $50.

1307. Misbranding of Fentone Compound. U. S. v. 31 Packages of Fentone Compound. Default decree of condemnation and destruction. (F. D. C. No. 12297. Sample No. 41524-F.)

On May 19, 1944, the United States attorney for the Southern District of Mississippi filed a libel against 31 packages of Fentone Compound at Jackson, Miss., alleging that the article had been shipped on or about August 5 and September 25, 1943, from Paris, Tenn., by the Fentone Medicine Co.

Examination showed that the article consisted essentially of water; Epsom salt; small proportions of sodium salicylate; iron, ammonium, and potassium compounds, including carbonates and phosphates; saccharin; oil of cinnamon; and a red coloring matter.

The article was alleged to be misbranded because of false and misleading statements on its label and in an accompanying circular entitled, "Is Intestinal Stasis Spreading Poisons Throughout Your System Contaminating the Blood-Stream, Liver and Kidneys?", regarding the efficacy of the article in the treatment of liver and kidney disorders, high blood pressure, rheumatism,

*See also Nos. 1304, 1305.

arthritis, nervousness, sleeplessness, backache, belching and bloating, stiff joints, heartburn, heart palpitation, swollen stomach, constipation, upset stomach, clogged liver, acid in the kidneys, packed colon, headache, dizziness, hyperacidity of the stomach and kidneys, indigestion, vomiting, nausea, a tired, worn-out feeling, frequent getting up at night, loss of vigor, neuritis, swollen joints, leg pains, coated tongue, bad breath, and toxemia.

The article was alleged to be misbranded further (1) in that its label failed to bear the common or usual name of each active ingredient; (2) in that its labeling failed to bear adequate directions for use; and (3) in that it was a laxative and its labeling failed to bear such warnings as are necessary for the protection of users.

On November 6, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1308. Misbranding of Garfield's Seidlitz Powders. U. S. v. 1,440 Packages of Garfield's Seidlitz Powders. Consent decree of condemnation. Product ordered released under bond to be relabeled. (F. D. C. No. 12175. Sample No. 77913-F.)

On April 12, 1944, the United States attorney for the Eastern District of Pennsylvania filed a libel against 1,440 packages of the above-named product at Philadelphia, Pa., alleging that the article had been shipped on or about December 24, 1943, by Garfield and Co., from New York, N. Y.; and charging that it was misbranded.

The article was alleged to be misbranded in that the labeling of 90 percent of the packages failed to bear warnings that the article should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present, and that frequent use of the preparation may result in dependence on laxatives to move the bowels.

On May 23, 1944, Garfield and Co., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond to be relabeled under the supervision of the Food and Drug Administration.

1309. Misbranding of Dependon Intrauterine Paste. U. S. v. 16 Packages of Dependon Intrauterine Paste. Default decree of condemnation and destruction. (F. D. C. No. 10437. Sample No. 10634-F.)

On August 19, 1943, the United States attorney for the Northern District of California filed a libel against 16 packages of the above-named product at Roseville, Calif., alleging that the article had been shipped on or about February 25, 1943, from White Bear Lake, Minn., by A. M. Jenks; and charging that it was misbranded. The article was unlabeled.

Examination of a sample disclosed that the article consisted essentially of soap, potassium iodide (1 percent), and water.

The article was alleged to be misbranded in that it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor; (2) an accurate statement of the quantity of contents; (3) the common or usual name of each active ingredient; and (4) adequate directions for its use.

On October 16, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

1310. Adulteration of crude drugs. U. S. v. 1 Bag of Elder Berries, 1 Bag of Peach Tree Leaves, and 8 Bags of White Pine Bark. Default decree of condemnation and destruction. (F. D. C. No. 11996. Sample Nos. 66225-F, 66228-F, 66229-F.)

On or about March 25, 1944, the United States attorney for the District of New Jersey filed a libel against 1 bag containing approximately 117 pounds of elderberries, 1 bag containing approximately 75 pounds of peach tree leaves, and 8 bags containing approximately 1,628 pounds of white pine bark at Jersey City, N. J., alleging that the articles had been shipped on or about January 24 and 26, 1944, from Boone, N. C., by the Wilcox Drug Co.; and charging that they were adulterated.

The white pine bark was alleged to be adulterated (1) in that it consisted in whole or in part of a filthy and decomposed substance by reason of the presence of worm-bored and moldy bark; and (2) in that it purported to be and was represented as a drug the name of which is recognized in the National Formulary, an official compendium, but its quality and purity fell

below the standard set forth therein, since the Formulary provides that vegetable drugs are to be as free from molds as practicable. The other articles were alleged to be adulterated in that they consisted in whole or in part of filthy substances by reason of the presence of rodent excreta and bird excreta in the elderberries, and rodent excreta in the peach tree leaves.

The articles were alleged to be further adulterated in that they had been prepared, packed, and held under insanitary conditions whereby they may have become contaminated with filth.

On June 5, 1944, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

1311. Adulteration of cough drops. U. S. v. 498 Cartons of Cough Drops (and 1 other seizure action against cough drops). Default decrees of condemnation and destruction. (F. D. C. Nos. 12476, 12630. Sample Nos. 40524-F, 40525-F, 71248-F.)

On or about June 5 and 6, 1944, the United States attorneys for the District of Oregon and the Northern District of Iowa filed libels against 498 cartons, each containing 40 packages, of cough drops at Portland, Oreg., and 9 cartons, each containing 12 packages, and 8 boxes, each containing 12 cartons of 12 packages each, of cough drops at Waterloo, Iowa, alleging that the article had been shipped between the approximate dates of February 16 and April 27, 1944, by the Ernest E. Johnson Co., from Minneapolis, Minn. The article was labeled in part: "Brystsukker Cough Drops," "Johnson's Extra Strong Horehound Drops," or "Brystsukker Danish Style Cough Drops."

The article was alleged to be adulterated in that it consisted in whole or in part of a filthy substance by reason of the presence of rodent and cat hairs, rodent excreta, and insect fragments; and in that it had been prepared under insanitary conditions whereby it may have become contaminated with filth.

On July 6 and 10, 1944, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

1312. Adulteration and misbranding of ampuls of Na-Iodide, sodium salicylate iodide with colchicine, sodium phenobarbital, and Najodyl. U. S. v. Solex Laboratories, Inc. Plea of guilty. Fine, $500 on 1 count; sentence suspended on 7 counts. (F. D. C. No. 11344. Sample Nos. 19029-F, 23415-F, 44655-F, 44658-F.)

On August 23, 1944, the United States attorney for the Southern District of New York filed an information against the Solex Laboratories, Inc., New York, N. Y., alleging shipment from the State of New York into the States of New Jersey and Pennsylvania of a quantity of the above-named products between the approximate dates of October 31, 1942, and May 28, 1943.

The Na-Iodide was alleged to be adulterated in that its strength differed from that which it was represented to possess, since it was represented on the carton and ampuls as containing 2 percent of sodium iodide, but it contained not more than 1.71 percent of sodium iodide. The article was alleged to be misbranded in that the statement on the labeling, "Sodium Iodide 2%," was false and misleading.

The sodium salicylate iodide with colchicine was alleged to be adulterated in that it purported to be and was represented as a drug the name of which, "Ampuls of Sodium Salicylate and Iodide with Colchicine," is recognized in the National Formulary, an official compendium, but its strength differed from the official standard in that the Formulary provides that ampuls of sodium salicylate and iodide with colchicine shall yield anhydrous sodium salicylate equal to not less than 93 percent of the labeled amount, whereas the article yielded anhydrous sodium salicylate equal to not more than 88.3 percent of the labeled amount, and its difference in strength from the standard was not plainly stated on the label. The article was alleged to be misbranded in that the statement "Sodium Salicylate * * * (15½ grs.)," on the ampuls containing the article, was false and misleading since the ampuls contained not more than 13.7 grains of sodium salicylate.

The sodium phenobarbital was alleged to be adulterated in that its strength differed from that which it was represented to possess, since it was represented on the carton and ampul labels as containing, in each ampul, .12

*See also Nos. 1302, 1303, 1310.

gram, equivalent to 2 grains of sodium phenobarbital, whereas it contained not more than .10 gram, equivalent to 1.67 grains of sodium phenobarbital. The article was alleged to be misbranded in that the statement "Sodium Phenobarbital .12 Gm. (2 grs.)," on the carton containing the ampuls, and the statement "2 grs. (.12 Gm.)," on the labels affixed to the ampuls, were false and misleading.

The Najodyl was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess, since it was represented on the carton and ampuls as containing 1 percent of sodium sulfate, but it contained not less than 1.81 percent of sodium sulfate. The article was alleged to be misbranded in that the statement "Sodium Sulfate 1%," on the labeling, was false and misleading.

On September 7, 1944, the defendant having entered a plea of guilty, the court imposed a fine of $500 on count 1, and suspended imposition of sentence on the remaining 7 counts.

1313. Adulteration and misbranding of Sumlakia. U. S. v. Otto Kalmus (The Sumlak Co.). Plea of guilty. Fine, $200. (F. D. C. No. 10559. Sample No. 8883-F.)

On April 7, 1944, the United States attorney for the Southern District of Ohio filed an information against Otto Kalmus, an individual trading as the Sumlak Co., Cincinnati, Ohio, alleging shipment of a quantity of Sumlakia on or about November 25, 1942, from the State of Ohio into the State of Louisiana.

The article was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess, since each teaspoonful of the article contained 10.18 grains of combined bromides, including 1.97 grains of strontium bromide, 2.01 grains of ammonium bromide, 1.96 grains of potassium bromide, and 3.93 grains of sodium bromide, which were in excess of the amounts declared, and 0.18 grain of calcium bromide and 0.13 grain of lithium bromide, which were less than the amounts declared.

The article was alleged to be misbranded (1) in that the statements on its labels, "Each teaspoonful contains approx. 8 Grains of the Six Combined Bromides of Strontium 1.80 gr., Ammonium 1.80 gr., Potassium 1.80 gr., Sodium 1.80 gr., Calcium 0.60 gr., Lithium 0.20 gr.," were false and misleading; and (2) because of false and misleading statements on its labels which represented and suggested that the article would be efficacious in the cure, mitigation, treatment, or prevention of functional nervous disturbances and hysterical conditions due to nervousness.

On November 17, 1944, the defendant entered a plea of guilty and was sentenced to pay a fine of $100 on each of 2 counts, a total fine of $200.

1314. Adulteration and misbranding of Hypno-Sedative. U. S. v. Brewer & Co., Inc. Plea of guilty. Fine, $100. (F. D. C. No. 12568. Sample No. 51349-F.)

On September 27, 1944, the United States attorney for the District of Massachusetts filed an information against Brewer & Co., Inc., Worcester, Mass., alleging shipment of a quantity of the above-named product on or about September 20, 1943, from the State of Massachusetts into the State of Rhode Island.

The article was alleged to be adulterated in that it purported and was represented to be compounded from chloral hydrate, potassium bromide, and extract of Hyoscyamus, whereas potassium iodide had been substituted in whole or in part for potassium bromide in compounding the article.

The article was alleged to be misbranded (1) in that the statement on its label, "Each fluid ounce contains * * * Potassium Bromide 96 grs.," was false and misleading since the article contained little, if any, potassium bromide, but did contain approximately 96 grains of potassium iodide in each fluid ounce; and (2) in that its label failed to bear the common or usual name of each active ingredient since it failed to declare the presence of potassium iodide in the article.

On November 29, 1944, a plea of guilty having been entered on behalf of the defendant, the court imposed a fine of $100.

1315. Adulteration and misbranding of calcium gluconate. U. S. v. 40 Dozen Cartons of Calcium Gluconate. Default decree of condemnation and destruction. (F. D. C. No. 11136. Sample No. 58440-F.)

On November 20, 1943, the United States attorney for the Northern District of California filed a libel against 40 dozen cartons, each containing

12 ampuls, 10 cc. size, of calcium gluconate at San Francisco, Calif., alleging that the article had been shipped on or about October 26, 1943, by the Cheplin Biological Laboratories, Inc., from Syracuse, N. Y.; and charging that it was adulterated and misbranded.

Examination disclosed that the article was contaminated with living organisms and contained considerable amounts of undissolved material, whereas the United States Pharmacopoeia provides that it must be sterile and free from undissolved material.

The article was alleged to be adulterated in that it purported to be and was represented as calcium gluconate injection, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard.

The article was alleged to be misbranded in that the statements on the label, "Injectio Calcii Gluconatis, U.S.P. * * * Sterile," were false and misleading.

On May 20, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1316. Adulteration of dextrose solution. U. S. v. 96 Vials of Dextrose (D-Glucose). Default decree of condemnation and destruction. (F. D. C. No. 12321. Sample No. 67440-F.)

On May 8, 1944, the United States attorney for the Northern District of Ohio filed a libel against 96 vials, containing 100 cc. each, of dextrose solution at Canton, Ohio, alleging that the article had been shipped on or about February 22, 1944, by Cheplin Biological Laboratories, Inc., Syracuse, N. Y.; and charging that it was adulterated.

The article was alleged to be adulterated in that it purported to be and was represented as dextrose injection, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth therein since the article failed to comply with the tests for heavy metals.

On June 16, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1317. Adulteration of isotonic solution of sodium chloride. U. S. v. 78 Bottles of Isotonic Solution of Sodium Chloride. Default decree of condemnation and destruction. (F. D. C. No. 12758. Sample No. 59373-F.)

On June 26, 1944, the United States attorney for the Northern District of Illinois filed a libel against 78 bottles of the above-named product at Chicago, Ill., alleging that the article had been shipped on or about May 31, 1944, from Cleveland, Ohio, by the Continental Hospital Service Co.

The article was alleged to be adulterated in that it purported to be "No. 3—Sterile Isotonic Solution of Sodium Chloride for Parenteral Use," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its purity and quality fell below the standard set forth therein since the article was contaminated with undissolved material.

On October 11, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1318. Adulteration of sodium iodide ampuls. U. S. v. 3 Boxes, each containing 25 ampuls, 10 cc. size, of Sodium Iodide. Default decree of condemnation and destruction. (F. D. C. No. 12431. Sample No. 53717-F.)

On May 24, 1944, the United States attorney for the Southern District of California filed a libel against the above-mentioned product at Los Angeles, Calif., alleging that the article had been shipped on or about September 29, 1943, by the Columbus Pharmacal Co., from Columbus, Ohio; and charging that it was adulterated.

The article was alleged to be adulterated in that it purported to be and was represented as ampuls of sodium iodide, a drug the name of which is recognized in the National Formulary, an official compendium, but its quality and purity fell below the official standard since the article was not free from undissolved material.

On June 13, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1319. Adulteration of Phenarsine Hydrochloride with Sterile Distilled Water. U. S. v. 40 Packages of Phenarsine Hydrochloride with Sterile Distilled Water. Default decree of condemnation and destruction. (F. D. C. No. 11831. Sample No. 76110-F.)

On or about February 16, 1944, the United States attorney for the District of Connecticut filed a libel against 40 combination packages of the above-named product at New Haven, Conn., alleging that the article had been shipped on or about January 26, 1944, by the Winthrop Chemical Co., Inc., from New York, N. Y.; and charging that it was adulterated.

The article was alleged to be adulterated in that it purported to be and was represented as a drug, "Sterilized Distilled Water," and "Water for Injection," the names of which are recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since the article was contaminated with undissolved material.

On March 25, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1320. Adulteration of triple distilled water. U. S. v. 88 Vials of Triple Distilled Water. Default decree of destruction. (F. D. C. No. 12083. Sample No. 67036-F.)

On or about March 30, 1944, the United States attorney for the Western District of Missouri filed a libel against 88 vials of the above-named product at Kansas City, Mo., alleging that the article had been shipped on or about February 25, 1944, by the S. E. Massengill Co., from Bristol, Tenn.-Va.; and charging that it was adulterated. The article was labeled in part: "Sterile Triple Distilled Water For the Preparation or dilution of sterile solutions for parenteral use."

The article was alleged to be adulterated in that it purported to be a drug, "Sterilized Distilled Water," and "Water for Injection," the names of which are recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth therein since the article was not clear, but was contaminated with undissolved material.

On April 28, 1944, no claimant having appeared, judgment was entered ordering that the product be destroyed.

1321. Adulteration of triple distilled water. U. S. v. 80 Vials and 244 Vials of Triple Distilled Water. Default decrees of condemnation and destruction. (F. D. C. Nos. 12096, 12105. Sample Nos. 66234-F, 76268-F.)

On March 25 and 31, 1944, the United States attorneys for the District of New Jersey and the Middle District of Pennsylvania filed libels against 80 100-cc. vials and 244 100-cc. vials of the above-named product at Scranton, Pa., and Jersey City, N. J., respectively, alleging that the article had been shipped between the approximate dates of December 2, 1943, and February 23, 1944, by the Adson-Intrasol Laboratories, Inc., from Brooklyn, N. Y.; and charging that it was adulterated.

The article was alleged to be adulterated in that it purported to be and was represented as water for injection, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth therein since the article was not clear and did not meet the official test for pyrogens, but contained insoluble suspended material and pyrogenic substances.

On June 5 and September 6, 1944, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

1322. Adulteration of triple distilled water. U. S. v. 369 Vials of Triple Distilled Water. Default decree of condemnation and destruction. (F. D. C. No. 12836. Sample No. 76298-F.)

On June 30, 1944, the United States attorney for the Eastern District of New York filed a libel against 369 vials, each containing 100 cc., of the above-named product at Brooklyn, N. Y., alleging that the article had been shipped on or about May 2, 1944, by the McCloskey Drug Co., Inc., from Jersey City, N. J.

The article was alleged to be adulterated in that it purported to be water for injection, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth therein since the article was not clear and did not meet the official test for pyrogens, but contained insoluble suspended material and pyrogenic substances.

On July 27, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1323. Adulteration of prophylactics. U. S. v. Trutex Products, Inc., and Frank Fenwick. Pleas of guilty. Each defendant fined $300 and costs; sentence suspended against individual defendant. (F. D. C. No. 11363. Sample Nos. 1757-F, 1759-F, 47389-F.)

On April 18, 1944, the United States attorney for the Northern District of Ohio filed an information against Trutex Products, Inc., Cleveland, Ohio, and Frank Fenwick, vice president of the corporation, alleging shipment between the approximate dates of April 10 and July 14, 1943, from the State of Ohio into the State of Illinois of a quantity of prophylactics.

The article was alleged to be adulterated in that its quality fell below that which it purported and was represented to possess, since it purported to be and was represented as a prophylactic, but the article was ineffective for prophylaxis because of the presence of perforations or holes.

On June 19, 1944, pleas of guilty having been entered by the defendants, the court imposed a fine of $300 and costs against each defendant. The sentence of fine and costs against Frank Fenwick was suspended.

1324. Adulteration and misbranding of prophylactics. U. S. v. 32 Gross of Prophylactics (and 13 other seizure actions against prophylactics). Default decrees of condemnation and destruction. (F. D. C. Nos. 11963, 12291, 12292, 12327, 12513, 13059, 13191, 13204, 13234 to 13236, incl., 13278, 13354, 13390. Sample Nos. 8640-F, 39576-F, 52419-F, 60918-F, 60919-F, 63718-F, 67066-F, 67087-F, 67089-F, 67686-F, 67691-F, 72689-F, 76382-F, 79419-F, 79923-F, 87219-F.)

Between March 7 and August 26, 1944, the United States attorneys for the Southern District of New York, the Eastern and Western Districts of Missouri, the Southern District of West Virginia, the District of Minnesota, the Western District of North Carolina, the Southern District of California, the Middle District of Tennessee, the Western District of Kentucky, the Northern District of Alabama, the District of Maryland, and the District of Massachusetts filed libels against the following quantities of prophylactics: 32 gross at New York, N. Y.; 5-7/12 gross at St. Louis, Mo.; 134½ gross at Kansas City, Mo.; 31 gross at Huntington, W. Va.; 215-5/6 gross at Minneapolis, Minn.; 28 gross at Charlotte, N. C.; 242 gross at Los Angeles, Calif.; 46¾ gross at Nashville, Tenn.; 392 gross at Camp Campbell, Ky.; 42⅓ gross at Birmingham, Ala.; 43 gross at Boston, Mass.; and 1,725¾ dozen at Aberdeen Proving Ground, Md. It was alleged in the libels that the article had been shipped between the approximate dates of October 16, 1943, and July 26, 1944, by W. H. Reed and Co., from Atlanta, Ga., with the exception of the lot at Huntington, which was alleged to have been packed by that company and shipped from Kansas City, Mo., by the B and N Sales Co. The article was labeled in part: "Malecaps," "Genuine XXXXX Goldbeaters," "Red Pak," "Xcello's Prophylactics * * * Mfd. By The Killian Mfg. Co. Akron, Ohio," "Surete Prophylactics," "Golden Pheasant Prophylactics," or "Pan Tested Fine Quality."

Examination of samples disclosed that the article was defective in that it contained holes.

The article, with the exception of the Malecaps brand, was alleged to be adulterated in that its quality fell below that which it purported or was represented to possess.

The article, with the exception of a portion of the Red Pak brand, was alleged to be misbranded in the following respects: (Malecaps brand) the statements, "Malecaps A Liquid Latex Product carefully tested and manufactured to comply with the Federal Pure Food and Drug Act. Sold as an aid to prevent disease," were false and misleading since the article would not be effective as an aid in the prevention of such diseases as syphilis, chancroid, granuloma inguinale, and lymphogranuloma inguinale, and might afford only a limited protection against gonorrhea, because of its short length; and the reference to the "Federal Pure Food and Drug Act" created the misleading impression that the article complied with the provisions of the Federal Food, Drug, and Cosmetic Act; and (Goldbeaters. Xcellos, Surete, and Golden Pheasant brands, and a portion of the Red Pak brand) certain statements which represented and suggested that the article was efficacious for the prevention of disease, and (Pan brand) the statement, "Tested Fine Quality," were false and misleading since the article contained holes.

The article was alleged to be misbranded further in that the label of the Malecaps brand failed to contain an accurate statement of the quantity of contents in terms of numerical count, since the number contained in each envelope was not stated; and in that the label of the Goldbeaters brand failed to bear the name and address of the manufacturer, packer, or distributor.

Between March 29 and October 26, 1944, no claimant having appeared, judgments were entered condemning the product and ordering its destruction.

1325. Adulteration and misbranding of prophylactics. U. S. v. 19 Packages and 40½ Gross of Prophylactics. Decrees of destruction. (F. D. C. Nos. 12156, 13028. Sample Nos. 67053-F, 80829-F to 80831-F, incl.)

On or about April 11 and July 27, 1944, the United States attorney for the Western District of Missouri filed libels against 40½ gross of prophylactics and 19 packages, each containing 1 dozen, of the same product at Kansas City, Mo., alleging that the article had been shipped between the approximate dates of March 7 and June 6, 1944, by the Crown Rubber Sundries Co., from Akron, Ohio; and charging that it was adulterated and misbranded. The article was labeled in part: "Genuine Gold Beaters," "Tetratex Genuine Latex Prophylactics Mfd. By L. E. Shunk Latex Products Inc. Akron, Ohio," or "Genuine Latex * * * Apris Prophylactics Mfd. by The Killian Mfg. Co. Akron, Ohio."

Samples of the article were found to be defective because of the presence of holes.

The article was alleged to be adulterated in that its quality fell below that which it purported and was represented to possess.

It was alleged to be misbranded in that the statements in the labeling of one lot, "Prophylactics," and of the other lot, "for prevention of diseases" and "for the prevention of disease only," were false and misleading since the article contained holes. A portion of the product was further misbranded in that its label failed to bear the name and place of business of the manufacturer, packer, or distributor.

On July 28 and October 26, 1944, no claimant having appeared, judgments were entered ordering the product destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

DRUGS FOR HUMAN USE

1326. Misbranding of Sugretus and Sunol. U. S. v. Elmer J. Dailey (Dailey's Laboratories). Plea of not guilty. Tried to the jury. Verdict of guilty. Fine of $250 on count 1; imposition of sentence on count 2 suspended and defendant placed on probation for 5 years. (F. D. C. No. 11424. Sample Nos. 57639-F, 57640-F.)

On July 5, 1944, the United States attorney for the Southern District of California filed an information against Elmer J. Dailey, trading as Dailey's Laboratories, San Diego, Calif., alleging shipment of a quantity of the above-named products from the State of California into the State of Texas on or about August 14, 1943.

Analysis of a sample of the Sugretus disclosed that it consisted of dark gray, uncoated, compressed tablets with a slight aromatic odor, and that it contained plant material, probably cactus, together with an iron compound. It was alleged to be misbranded because of false and misleading statements on its label and in an accompanying circular letter headed "Dailey's Laboratories," which represented and suggested that the article would be efficacious in the cure, mitigation, treatment, or prevention of diabetes, Buerger's disease, and pancreas, liver, and kidney troubles; that it would make diabetics sugar-free and keep them so; that its use would enable persons who were using insulin and dieting to live normal lives, i.e., give up insulin and dieting; and that it would build up the pancreas, liver, and kidneys.

Analysis of a sample of the Sunol disclosed that it consisted essentially of volatile oils including oil of eucalyptus, camphor, and thymol dissolved in a fatty oil. The article was alleged to be misbranded in that the statement, "For soreness in Bunions," borne on its label, was false and misleading since the article would not be efficacious in the cure, mitigation, treatment, or prevention of soreness in bunions; and in that its label failed to bear any statement of the quantity of the contents or of the active ingredients of the article.

On July 15, 1944, the defendant entered a plea of not guilty, and on September 5, 1944, the case came on for trial before a jury. The trial was concluded on September 7, 1944, on which date the court delivered the following instructions to the jury:

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*See also Nos. 1301-1307, 1312-1315, 1324, 1325.

LING, *District Judge*: "It now becomes the court's duty, gentlemen, to instruct you with reference to the law that applies to this particular case.

"This criminal proceeding was brought under the provisions of the Federal Food, Drug and Cosmetic Act, which was intended to prevent the movement in interstate commerce of adulterated and misbranded foods, drugs, devices and cosmetics.

"The statute prohibits the introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

"In this case the government in Count I charges defendant with unlawfully introducing and delivering for introduction into interstate commerce three bottles containing an article known as 'Sugretus.'

"The government alleges the article to be misbranded in violation of the statute and a drug within the meaning of the statute.

"Count II charges the same transaction with respect to another article known as 'Sunol.'

"The government alleges this article to be misbranded in violation of the statute and a drug within the meaning of the statute.

"In Count II the government further alleges that the label failed to bear an accurate statement of the quantity of the contents and further that the said label failed to bear the common or usual name of the active ingredients, in violation of the statute.

"The Food, Drug, and Cosmetic Act provides that an article can be misbranded in a number of different ways. In Count I of this Information, that is with respect to the article 'Sugretus,' the government has confined its charges to false and misleading statements. An article can be misbranded, however, in other ways.

"In Count II of this Information, the government has set forth three different ways in which this article is misbranded.

"First: It is alleged that the article is misbranded because of certain statements which it alleges are false and misleading.

"Second: It is alleged that the article is misbranded because the label fails to bear a statement as to the quantity of contents.

"Third: It is alleged that it is an article fabricated from two or more ingredients, and fails to bear a statement as to the common or usual name of each active ingredient.

"It is not necessary that you find from the evidence that the article is misbranded in all three of these ways. If you should find that the article is misbranded in any one of these three manners, then you must find the defendant guilty under Count II. If, for example, from the evidence you find that the article 'Sunol' fails to bear a statement on its label of the quantity of contents, or that it is fabricated from two or more ingredients and fails to bear a statement of the common or usual name of active ingredients, then you must find the defendant guilty with respect to Count II whether or not you believe that the statements alleged to be false and misleading are in fact false and misleading.

"If you find from the evidence that in any particular this drug is misbranded, then the law has been violated. It is not necessary that every misbranding be proved.

"There is no dispute that the articles set forth in the information were shipped in interstate commerce by the defendant as alleged.

"It has been stipulated that the articles were introduced and shipped in interstate commerce.

"I, therefore, charge you that the sole question for you to determine from the evidence in the case, is whether or not there was a misbranding in violation of the statute, as alleged by the government.

"If, after hearing the evidence in this case, you reach the conclusion as to Count I that the drug or product known as 'Sugretus' was harmless, that does not excuse the defendant if you find that he placed statements upon said article or drug which were false concerning curative, therapeutic, and mitigating effects of said product, as the danger and injury to the public from representations of this kind is considerable, in that it induces persons frequently to rely in serious cases upon preparations without healing virtue when, but for this reliance, they would no doubt secure proper advice and treatment for the illnesses which affect them.

"With respect to Count II of the Information, you are instructed that the

term 'relief' is not of definitive connotation or entirely free from ambiguity; in a common sense it connotes permanent removal of organic or functional disturbance as distinguished from alleviation of discomfort. The representation that an article or drug is 'for' or a 'treatment for' a disease is equivalent to labeling it as a cure or remedy.

"The statute under which this case has been tried condemns every statement in the labeling of the article 'Sugretus,' and the article 'Sunol' which may mislead or deceive. Deception may result from the use of statements not technically false or which may be literally true. The aim of the statute is to prevent that resulting from indirection and ambiguity, as well as from statements that are false. It is not difficult to choose statements that will not deceive.

"If you find from the evidence that there are any false and misleading statements in the labeling involved in this case, your verdict should be for the government, as I have stated before.

"In determining whether or not any statements made in the labeling of 'Sugretus' and 'Sunol' are misleading, you should take into account, among other things, not only representations made or suggested by such statements, but also the extent to which the labeling may fail to reveal facts material in the light of such representations.

"If you find from the evidence that there is a material weight of medical and scientific opinion contrary to any of the representations made in labeling 'Sugretus' or 'Sunol,' you may find that said articles are misbranded.

"If you find that the circular introduced in evidence in this case, and contained in the package admitted to have been shipped in interstate commerce by the defendant, as alleged in Count I, contains statements describing the curative, therapeutic or mitigating effects of the article or drug, and find that such statements are likely to mislead in any particular, you should find the defendant guilty of misbranding on Count I.

"What these labels and circular mean, you are to test by taking the language of each of them and imparting to that language the meaning of the words singly and together that would be conveyed to you as ordinary men, not as men who are skilled in medical, chemical, or pharmaceutical science capable of making nice distinctions or nice discriminations, but rather the meaning that comes to you as ordinary men unskilled, but seeking, we will assume, some sort of remedy or remedial help from the afflictions that flesh is heir to. Now, in that connection, you should examine the language used in the light of the purpose of this law, which is to protect human kind against the consequence of human weakness, or human failing, or human credulity, or the disposition to believe, or of human gullibility. You should examine it in the light of the disposition of the ordinary human kind to wish to believe in the potency of remedial agents to relieve them of ills from which they are actually or conceivably suffering.

"Under the Food and Drug Act the term 'drug' includes any substance or mixture of substances intended to be used for the cure, mitigation or prevention of diseases of mankind. The aim of the Act is to prevent indirection and ambiguity in the labeling of drugs, as well as to prevent statements which are literally false. It is not difficult to choose statements, designs, or devices concerning the curative, therapeutic or mitigating effect of any article or drug which will not deceive. Those which are ambiguous or likely to mislead should be read favorably to the accomplishment of the purposes of the Act, and if you find the labels and circular used by the defendant, Elmer J. Dailey, describing the curative, therapeutic and mitigating effect of the articles or drugs 'Sugretus' and 'Sunol' contain statements that are likely to mislead, in any particular, you should find the defendant guilty of misbranding.

"Of course, if you do not so find, you should find the defendant not guilty.

"Witnesses, those who are supposed to know more than the ordinary person about such subjects, such as chemists and physicians, have been permitted to give their opinions as to various matters. Opinion evidence is not binding upon you, but should be considered in connection with all other evidence in this case. Should you believe it, you may accept and follow it. By an opinion, I mean a statement or a conclusion arrived at by the witness from experience or from knowledge, as distinguished from testimony concerning the direct fact.

"That is, I might say that this building was constructed of brick. That

would be a statement of fact. If I would say it was worth twenty thousand or a hundred thousand dollars, that would merely be my opinion.

"You are the sole judges of the value of opinion evidence. Of course, an opinion is worthless unless it is the honest opinion of the man who states it. If you deem it is his honest opinion, then its value depends upon how much he knows about the subject concerning which he is testifying. If he is fairly experienced, fairly grounded in his subject, if his opinion is the result of mature reflection, if he is a man of strong logical intellect, his opinion would be entitled to great value. If, on the other hand, he is incapable of logical thinking, or if he is not well grounded in his subject, nor familiar with the facts upon which his conclusion is assumed to be based, then, of course, his opinion would be of little or no value; and it is for you to decide what value you will give to the opinion evidence that you have heard.

"It is not necessary for the government to prove the defendant intentionally misbranded the articles in any particular. Intent is immaterial in a charge of misbranding as is charged in this case.

"So, if you find from the evidence that the labels and circular contained false and misleading statements in any particular, then you must render your verdict accordingly.

"Now, a great deal of the evidence of the witnesses who have testified concerning their own ailments is in the nature of opinion evidence. Those witnesses who testified that they had well-known, easily discernible diseases, or easily-told diseases, I will say, such as headaches and constipation, or something of that sort, of course, there will be very little reason to doubt that they knew what they had. But if one testified that he thought he had some more obscure disease, more difficult to diagnose, and his diagnosis of what he had depended entirely upon his own opinion, and he was unable to make such a diagnosis, his opinion would be of very little value. Those are matters for you to take into consideration in weighing the testimony of the witnesses.

"You are the sole judges of the facts of this case, also of the credibility of each and every witness who has testified before you, and the weight that you will give his testimony. In determining the credibility of any witness you have a right to take into consideration his or her manner and appearance while giving his or her testimony, his or her means of knowledge of the facts to which he or she has testified; any interest or motive he or she may have for his or her testimony, if shown, and the probability or improbability of the truth of his or her statements when measured in connection with all other evidence in the case. If you believe that any witness has wilfully sworn falsely as to any material fact, then you have a right to wholly disregard the testimony of such witness, except insofar as the same may be corroborated by other credible evidence or by facts and circumstances proven or admitted in the case.

"In order to convict the defendant of the crime charged in the indictment, it is incumbent upon the government to prove to you beyond a reasonable doubt and to a moral certainty the truth of each and every material allegation of the indictment. The law raises no presumptions against a defendant, but every presumption of law is in favor of his innocence.

"A reasonable doubt as applied to evidence in criminal cases, is such a doubt as you may entertain as reasonable men after a thorough review and consideration of all the evidence, a doubt for which a reason arising from the evidence, or from the want of evidence, exists. It is not, however, a fanciful conjecture of the mind, nor the mere possibility of a doubt, but it is a substantial, well-founded doubt. It is that state of the case which, after a full and fair review of all the evidence, leaves the mind of a juror in such condition that he cannot say he feels an abiding conviction to a moral certainty of the guilt of the accused. It is an actual, sincere mental hesitation caused by insufficient or unsatisfactory evidence.

"While it is true that the government is required to prove the guilt of the defendants beyond a reasonable doubt, it is not required to prove their guilt to a mathematical certainty. All that the court and the jury can act upon is belief to a moral certainty and beyond a reasonable doubt.

"Now, if, after fully and fairly considering all of the evidence in this case you entertain such a reasonable doubt as I have defined as to the guilt or innocence of this defendant, then it becomes your duty to resolve that doubt in favor of the defendant and to return a verdict of not guilty. On the

other hand, if, after so considering all of the evidence in the case you are satisfied beyond a reasonable doubt and to a moral certainty that the defendant has committed the acts as charged and constituting the crime set forth in the Information, then it becomes your duty to render a verdict of guilty.

"After you retire to the jury room you will select one of your number to act as foreman, and you will proceed with your deliberation. After you had agreed upon a verdict you will have it signed by your foreman and return it to open court. And any verdict rendered, of course, will be the unanimous verdict of the jury.

"A form of verdict has been prepared for your guidance."

The jury thereupon retired and, after due deliberation, returned a verdict of guilty. On September 15, 1944, the court imposed a fine of $250 on count 1 and suspended the imposition of sentence on count 2, placing the defendant on probation for 5 years.

1327. Misbranding of Tesano Tea. U. S. v. Tesano Tea Co., Inc., and Elmer H. Baden. Pleas of guilty. Corporate defendant fined $50, which fine was remitted. Individual defendant fined $200, which fine was paid. (F. D. C. No. 7313. Sample Nos. 79774-E, 90432-E.)

On July 18, 1944, the United States attorney for the Southern District of New York filed an information against the Tesano Tea Co., Inc., New York, N. Y., and Elmer H. Baden, alleging shipment of quantities of Tesano Tea on or about February 13 and 16, 1942, from the State of New York into the States of Ohio and Connecticut.

Analysis of a sample of the article disclosed that it consisted essentially of plant material, including senna leaves, Vaccinium leaves, yarrow herb, sweet clover, Malva flowers, chamomile flowers, fennel seed, and anise seed.

The article was alleged to be misbranded because of false and misleading statements in its labeling which represented and implied that the article would be efficacious in the treatment, mitigation, and relief of diabetes and kidney and bladder disorders; that it would aid the regenerative forces of the human body in bringing about a more normal condition; and that it would improve the health and bring about a general improvement in the conditions of persons suffering from diabetes and kidney and bladder disorders. The article would not be efficacious for the purposes claimed.

On August 11, 1944, a plea of guilty having been entered on behalf of the corporate defendant, the court imposed a fine of $50. On October 13, 1944, the individual defendant entered a plea of guilty and was fined $100 on each of 2 counts, a total fine of $200. The fine imposed on the corporation was remitted.

1328. Misbranding of Doradil. U. S. v. 19 Bottles of Doradil. Default decree of condemnation and destruction. (F. D. C. No. 12478. Sample No. 35263-F.)

On or about June 12, 1944, the United States attorney for the Southern District of Florida filed a libel against 19 bottles of Doradil at Tampa, Fla., alleging that the article had been shipped on or about December 11, 1943, and January 6 and 18, 1944, by the Ulrici Medicine Co., Inc., from New York, N. Y.

Examination disclosed that the article consisted essentially of rhubarb extract; sodium phosphate, approximately 1.3 percent; potassium iodide, approximately 0.23 percent; alcohol, 7 percent; and water.

The article was alleged to be misbranded because of false and misleading statements, appearing in an accompanying circular entitled "Doradil of Ulrici," regarding its efficacy in treating liver complaints, hepatitis, congestion, biliousness, bilious diarrhea, and constipation, and its efficacy in maintaining the correct hepatic activity, stimulating the biliary secretion, toning the liver, regulating the digestive process, and combating many causes of obstruction and flatulence. The article was alleged to be misbranded further in that the common or usual name of each active ingredient in the article, required by law to appear on the label, was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, and devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, since the information did not appear in the English language on the carton and did not appear at all upon the bottle label, and the names of the active ingredients, which were given in the Spanish language, were intermingled with the names of inactive ingredients so as

not to indicate to the ordinary purchaser which of the ingredients were active.

On July 17, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1329. Misbranding of Formula No. 4 and Formula No. 13. U. S. v. 94 Packages of Formula No. 4 and 52 Packages of Formula No. 13. Default decree of condemnation and destruction. (F. D. C. No. 11447. Sample Nos. 53826-F, 53828-F.)

On December 22, 1943, the United States attorney for the District of Arizona filed a libel against 94 packages of Formula No. 4 and 52 packages of Formula No. 13 at Tucson, Ariz., alleging that the articles had been shipped on or about November 9, 1943, by the Dietary Research Laboratories, Los Angeles, Calif.; and charging that they were misbranded. The articles were labeled in part: "Supplemental Concentrates Formula No. 4 20 Vegetable Concentrates Combined with Raw Liver, Heart Muscle and Stomach Lining Vitamins A, B, D, E and G Present in their Natural Form," and "Formula No. 13 Garlic—Parsley."

Examination of the Formula No. 4 disclosed that it consisted essentially of alfalfa and wheat with small amounts of other vegetable material and possibly animal tissue. It was alleged to be misbranded in that the statements in the labeling, "The materials for this tablet were selected for their properties of blood regeneration. A healthy blood stream is the first basic requirement of health," were false and misleading since the article would not be effective in regenerating blood or in producing a healthy blood stream.

Examination of the Formula No. 13 disclosed that it consisted essentially of garlic and parsley. It was alleged to be misbranded in that the statements in the labeling, "A Dietary Supplement in the presence of High Blood Pressure," and "A dietary supplement processed and formulated to provide an effective adjuvant to the regular or prescribed diet," were false and misleading since the article would not be effective in relieving high blood pressure, and was not an adjuvant to the diet.

The articles were also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

On February 7, 1944, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

1330. Misbranding of wheat germ. U. S. v. 88 Packages of Wheat Germ. Default decree of condemnation and destruction. (F. D. C. No. 12680. Sample No. 75714-F.)

On June 17, 1944, the United States attorney for the Northern District of Ohio filed a libel against 88 1-pound packages of wheat germ at Warren, Ohio, alleging that the article had been shipped on or about April 14, 1944, by the Triple Health Food Co., Rochester, N. Y. The article was labeled in part: "Triple Health (Superior) Wheat Germ * * * A Natural Medicinal Food."

Examination showed that the article was essentially wheat germ. It was alleged to be misbranded in that the label statements, "Triple Health A Vitality-Filled Body A Cheerful Mind * * * A Peaceful Spirit The Triple Health System * * * A Natural Medicinal Food * * * Twice as rich in protein as meat. Contains vitamins A, * * * E and G. Rich in organic minerals. Recommended as a physical builder. Nerve and mental tonic. Digestive and eliminative aid. Beneficial in skin conditions, etc. * * * Triple Health Food," were false and misleading since the article was not a medicinal food, would not effect the results suggested and implied, would provide nutritionally inconsequential amounts of vitamins A, E, and G, was not rich in organic minerals, and was not twice as rich in protein as meat.

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

On August 7, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1331. Misbranding of Harris' 121 Remedy. U. S. v. 26 Bottles and 10 Bottles of Harris' 121 Remedy. Default decree of condemnation and destruction. (F. D. C. No. 12477. Sample No. 28865-F.)

On or about June 12, 1944, the United States attorney for the Southern District of Florida filed a libel against 26 small size bottles and 10 large size bottles of the above-named product at Orlando, Fla., alleging that the article had been shipped by the Harris Medicine Co., from Dawson, Ga., on or about

April 7, 1944. The article was labeled in part: "Harris' 121 Remedy Alterative and Stomachic Tonic."

Examination of a sample disclosed that the article consisted essentially of a solution in water of potassium iodide, 11.4 grains per fluid ounce, arsenic trioxide, 0.007 grain per fluid ounce, mercuric chloride, 0.045 grain per fluid ounce, and a bitter drug such as gentian extract.

The article was alleged to be misbranded because of false and misleading statements, appearing in an accompanying circular entitled "Get the Poison Out of Your System . . . Take Harris' 121 Remedy," regarding the efficacy of the article in eliminating poison from the system, building up the system, restoring strength, health, and the health functions of the body, fortifying the system against many diseases, and treating rheumatism, flu aftermath, thick blood, pimples, boils, muscular aches and pains, swollen glands, and rheumatic pains.

On August 17, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1332. Misbranding of Fero-B-Plex, Minerals Plus, sarsaparilla root U.S.P. with sassafras bark, Cetabs, fenugreek tea, and BoLax Laxatives Tablets. U. S. v. 141 Packages of Fero-B-Plex, 4 Packages of Minerals Plus, 9 Packages of Sarsaparilla Root U.S.P. with Sassafras Bark, 8 Packages of Cetabs, 11 Packages of Fenugreek Tea, 46 Packages of BoLax Laxative Tablets, and a number of booklets. Default decree of condemnation and destruction. (F. D. C. No. 12078. Sample Nos. 70727-F, 70728-F, 70767-F to 70771-F, incl.)

On April 3, 1944, the United States attorney for the Western District of Washington filed a libel against the above-mentioned products at Seattle, Wash., alleging that they had been shipped between the approximate dates of July 15, 1942, and January 20, 1944, by LeLord Kordel and LeLord Kordel Products from Chicago, Ill.; and charging that they were misbranded.

Analysis disclosed that the Fero-B-Plex contained iron, calcium, phosphorus, vitamin B_1, vitamin B_2, and niacin; that the Minerals Plus contained calcium, phosphorus, iron, iodine, and vitamin D; that the sarsaparilla root U.S.P. with sassafras bark consisted essentially of sarsaparilla root and a small proportion of sassafras bark; that the Cetabs contained 31 milligrams of ascorbic acid per tablet; that the fenugreek tea consisted essentially of fenugreek seeds; and that the BoLax Laxative Tablets consisted essentially of powdered plant material including laxative plant drugs such as senna and buckthorn.

The articles were alleged to be misbranded in that the statements in an accompanying booklet entitled, "What You Can Do About Relieving the Agonies of Arthritis," which represented and implied that the articles were of value in the treatment of arthritis were false and misleading since they were not of value in the treatment of arthritis whether taken alone, in combination, or in conjunction with certain diets recommended in the labeling.

The articles were also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

On September 30, 1944, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

1333. Misbranding of Hale's Honey of Horehound and Tar, and Glenn's Sulphur Soap. U. S. v. 22 Packages and 52 Packages of Hale's Honey of Horehound and Tar, and 190 Boxes of Glenn's Sulphur Soap. Default decree of condemnation and destruction. (F. D. C. No. 12114. Sample Nos. 66238-F, 66239-F, 77214-F.)

On April 13, 1944, the United States attorney for the Southern District of New York filed a libel against 22 packages, containing 2 fluid ounces each, and 52 packages, containing 4 fluid ounces each, of Hale's Honey of Horehound and Tar, and 190 boxes, each containing 3 cakes, of Glenn's Sulphur Soap at New York, N. Y., alleging that they had been shipped on or about February 8 and 23, 1944, by the Century National Chemical Co., from Paterson, N. J.; and charging that they were misbranded.

Examination of the Hale's Honey of Horehound and Tar showed that it contained tar, chloroform, and syrup.

The article was alleged to be misbranded because of false and misleading statements in the labeling which represented and suggested that the article was effective for coughs, colds, hoarseness, whooping cough, sore throat, loss of voice, or inflamed or irritable conditions of the respiratory mucous membranes.

Examination of the Glenn's Sulphur Soap showed that it was a soap containing sulfur.

The article was alleged to be misbranded because of false and misleading statements in the labeling regarding the efficacy of the article in the treatment of skin infections in general, chronic eczema, pimples, skin eruptions, and blackheads, and in bringing about a healthful condition.

On May 9, 1944, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

1334. Misbranding of Kloronol. U. S. v. 130 Packages and 140 Bottles of Kloronol. Default decrees of condemnation and destruction. (F. D. C. Nos. 12707, 13403. Sample Nos. 77785-F, 85006-F, 85007-F.)

On June 19 and August 29, 1944, the United States attorney for the Eastern District of Pennsylvania filed libels against 130 packages and 140 bottles, each containing 1 fluid ounce, of Kloronol at Philadelphia, Pa., alleging that the article had been shipped from New York, N. Y., by the Sumlar Co., between the approximate dates of January 21 and June 26, 1944.

Analysis showed that the article consisted essentially of small quantities of ephedrine sulfate, epinephrine hydrochloride, chlorobutanol, thymol, eucalyptol, methyl salicylate, potassium bicarbonate, and borax, dissolved in water and colored red.

The article was alleged to be misbranded because of false and misleading statements on its labels and in the accompanying circulars entitled, "Prompt Relief from Acute Discomforts of Sinus Trouble Head Colds," and "Evidence of Results," regarding the efficacy of the article in relieving sinusitis and the acute discomforts of head colds. The article was alleged to be misbranded further in that the warnings required by law to appear on the labeling were not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use, since the warnings had been printed in type of a very inconspicuous size at the bottom of the first page of the circular.

On July 12 and October 10, 1944, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

1335. Misbranding of Dr. E. R. Moras' Eyecream. U. S. v. 6 Packages of Dr. E. R. Moras' Eyecream. Default decree of condemnation and destruction. (F. D. C. No. 12157. Sample No. 54034-F.)

On April 10, 1944, the United States attorney for the Southern District of California filed a libel against 6 packages of the above-named product at Los Angeles, Calif., alleging that the article had been shipped on or about March 1, 1944, by Dr. E. R. Moras from Highland Park, Ill.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of petrolatum and lanolin containing vitamins A and B.

The article was alleged to be misbranded in that the statement on its label, "Eyecream treatment has proved helpful in eye strain and many of its symptoms and in dispensing with glasses," was false and misleading since the article would not be effective to produce the results claimed; and in that the statements in accompanying circulars entitled "Detoxication, Elimination Nutrition, Why Detoxyl," "How to Use Eyecream and Your Eyes," and "Eye Truths," which represented and suggested that the article would relieve eyestrain and its various symptoms, relieve or cure granulated lids, sties, and astigmatism, penetrate the mechanism of the eye, strengthen or restore eyesight to normal, remedy sore or inflamed eyes, obviate the necessity for wearing glasses, or the need for stronger glasses, enable the user to dispense with glasses, prevent or relieve cataract, and prevent loss of eyesight and dim, blurring sight, were false and misleading since the article contained no ingredient or combination of ingredients which would be effective to produce the results stated and implied.

On May 9, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1336. Misbranding of Nox-A-Boil Tablets. U. S. v. 17 Packages and 48 Vials of Nox-A-Boil Tablets. Default decree of condemnation and destruction. (F. D. C. No. 12333. Sample Nos. 59774-F.)

On June 5, 1944, the United States attorney for the Northern District of Illinois filed a libel against 17 60-tablet packages and 48 30-tablet vials of Nox-A-Boil Tablets at Chicago, Ill., alleging that the article had been shipped between the approximate dates of February 27, 1943, and March 27, 1944, by the Noxaboil Laboratories, from Fenton, Mich.

Analysis indicated that the article contained principally starch, sugars, calcium carbonate, fat, silica, and small proportions of other constituents, including magnesium and phosphorous compounds.

The article was alleged to be misbranded in that the designation "Nox-A-Boil," the firm name "The Noxaboil Laboratories," and certain statements in the labeling, were false and misleading since they represented and suggested that the article would be an adequate treatment for boils, pimples, carbuncles, furuncles, infected lacerations, sprains, bruises, cuts, abscesses, ulcerated teeth, sore throat, tonsilitis, canker sores in the mouth, discharging ears, infected wounds, and other septic infections, whereas it would not be efficacious for such purposes. It was alleged to be misbranded further in that it failed to bear labels containing an accurate statement of the quantity of the contents of the package and vial.

On July 24, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1337. Misbranding of Kotalko. U. S. v. 1½ Dozen Packages of Kotalko. Default decree of condemnation and destruction. (F. D. C. No. 12165. Sample No. 50272-F.)

On April 10, 1944, the United States attorney for the Western District of Pennsylvania filed a libel against 1½ dozen packages of Kotalko at Pittsburgh, Pa., alleging that the article had been shipped on or about January 13, 1944, by the Block Drug Co., from Jersey City, N. J.; and charging that it was misbranded.

Examination showed that the article consisted essentially of an ointment containing, among other ingredients, turpentine and a camphoraceous oil. The box containing the ointment occupied only 32.1 percent of the volume of the carton. The average net weight of the ointment in the box was 0.86 ounce, which was 37.8 percent below the declared 1⅜ ounces.

The article was alleged to be misbranded (1) in that the statements in the circulars entitled, "Kotalko Dictory" and "Important Truth Revealed," enclosed in the carton containing the article, which represented and suggested that the article would encourage hair growth, decrease dandruff, retard excessive hair loss, beautify the hair, maintain healthy, beautiful hair growth, stimulate and invigorate the scalp circulation, and encourage the hair roots into active vitality, were false and misleading since the preparation contained no ingredients or combination of ingredients capable of producing the effects stated or implied; (2) in that it was in package form and its label failed to bear an accurate statement of the quantity of the contents, since the statement which appeared on the label was incorrect; and (3) in that its container was so made, formed, or filled as to be misleading, since the carton was materially larger than was necessary to hold the contents.

On May 15, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1338. Misbranding of Obeto. U. S. v. 1,175 Ampuls of Obeto. Default decree of condemnation and destruction. (F. D. C. No. 12955. Sample No. 53727-F.)

On July 15, 1944, the United States attorney for the Southern District of California filed a libel against 1,175 ampuls of Obeto at Los Angeles, Calif., alleging that the article had been shipped on or about March 23, 1944, by the Ziegler Pharmacal Co., from Buffalo, N. Y.

Examination showed that the article was a water solution in ampuls, each cubic centimeter of which contained an extract from 1 grain of thyroid.

The article was alleged to be misbranded (1) in that it was fabricated from two or more ingredients and was not designated solely by a name recognized in an official compendium, and its label failed to bear a statement of the quantity or proportion of thyroid or a preparation of thyroid contained therein; and (2) in that the statement on the carton containing the article, "Active principles of adrenal cortex, anterior pituitary, thyroid, ovarian, lymphatic, pituitary posterior, thymus," was misleading since the

active principles of adrenal cortex, anterior pituitary, ovarian, and posterior pituitary were not present in the article in significant proportions, if at all, and since lymphatic and thymus tissues contain no known active principles.

On August 24, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1339. Misbranding of Magnetic Ray appliances. U. S. v. 8 Magnetic Ray Devices and 100 Circulars, and 3 Magnetic Ray Devices and Circulars. Default decrees of condemnation. Four devices and 2 sets of circulars ordered delivered to the government; remainder ordered destroyed. (F. D. C. Nos. 11863, 12046. Sample Nos. 9262-F, 59455-F.)

On or about March 14 and 23, 1944, the United States attorneys for the Western Districts of Michigan and Louisiana filed libels against 8 Magnetic Ray devices and 100 circulars at Muskegon, Mich., and 3 Magnetic Ray devices and a number of circulars at Lake Charles, La. On May 18, 1944, a supplemental libel was filed against 3 more of the devices at Lake Charles, La. It was alleged in the libels that a number of the devices had been shipped between the approximate dates of December 3, 1943, and January 12, 1944, by Frank B. Moran, trading as the Magnetic Ray Co., from Dallas, Tex., to Muskegon, Mich.; that the remainder had been consigned by that shipper to Orange, Tex., and from there transported by the consignee, Mrs. John Martin, to Lake Charles, La., on or about February 28, 1944; and that the devices, when introduced into and while in interstate commerce, were accompanied by circulars entitled "Magnetic Ray Treatment," and "Directions for Taking Magnetic Ray Treatments."

The device consisted of a coil of wire made in the form of a belt, to which was fastened a wire to be connected with an ordinary lighting circuit. When so connected it would produce a magnetic field.

The device was alleged to be misbranded because of false and misleading statements in the accompanying circulars which represented and suggested that it would be efficacious in the treatment of asthma, arthritis, anemia, Bright's disease, bladder trouble, bronchitis, colds, hay fever, constipation, catarrh, catarrhal deafness, diabetes, eczema, epilepsy, goiter, hemorrhoids, heart diseases, headaches, high blood pressure, indigestion, insomnia, impotence, low blood pressure, lumbago, menstrual troubles, neuralgia, neuritis, nervous troubles, obesity, paralysis, rheumatism, sciatica, sinus troubles, tuberculosis, tumors, ulcers, varicose veins, prostate disorders, and affections of the pelvic organs; that it would promote sound and refreshing sleep, relieve nervous irritability and pain, and exert a revitalizing influence upon the sexual or procreative glands; that it would increase physical and mental efficiency, clear the complexion, tone up the system, restore and preserve health, cause the absorption of abnormal growths and deposits, such as tumors, goiter, and blood clots, and improve circulation; and that it would be effective to avoid and eliminate autotoxemia. The article would not be efficacious for such purposes.

On April 8 and December 7, 1944, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed, with the exception of a number of the devices and circulars, which were ordered delivered to the government.

DRUGS FOR VETERINARY USE

1340. Misbranding of Pom-U-Soy. U. S. v. Pom-U-Soy Co., Ltd. Plea of guilty. Fine, $100. (F. D. C. No. 12559. Sample No. 47851-F.)

On October 27, 1944, the United States attorney for the Southern District of Ohio filed an information against the Pom-U-Soy Co., Ltd., a partnership, Cincinnati, Ohio, alleging shipment of a quantity of the above-named product on or about November 15, 1943, from the State of Ohio into the State of Arkansas.

Analysis of a sample of the article showed that it consisted essentially of water, containing extracts of plant drugs.

The article was alleged to be misbranded because of false and misleading statements on its label and in an accompanying circular entitled, "Read What Users Say About 'Pom-U-Soy'," which represented and suggested that the article would be efficacious in the cure, mitigation, treatment, and prevention of coccidiosis and blood disorders; that it would afford protection continuously, from hatching through the life of the poultry; that it would be efficacious as an everyday health builder for a laying flock, and as a disease

preventive for chickens; that it would keep the laying flock in good condition, insure that the flock would eat right, keep infection from the poultry flock, and cause chickens to drink more water and feather out better; that it was an all-around cure for chicken diseases; and that it would be efficacious in the correction of blood in the droppings. It would not be efficacious for such purposes.

On November 17, 1944, a plea of guilty having been entered on behalf of the defendant, the court imposed a fine of $100.

1341. Misbranding of Mor-Milk for Pigs and Hogs, Mor-Milk for Calves, and Mor-Milk for Poultry. U. S. v. Utley Noble (Mor-Milk Co.). Plea of guilty. Fine, $50 on each count, a total fine of $450 and costs. (F. D. C. No. 11335. Sample Nos. 32090-F, 32091-F, 37312-F, 37967-F.)

On April 17, 1944, the United States attorney for the Northern District of Illinois filed an information against Utley Noble, trading as the Mor-Milk Co., Dixon, Ill., alleging shipment of a quantity of the above-named products between the approximate dates of February 2 and April 30, 1943, from the State of Illinois into the States of Indiana, Pennsylvania, and Michigan.

Analysis of the Mor-Milk for Pigs and Hogs showed that the product consisted of a pink powdered material containing, chiefly, starch, protein, water, crude fiber, and small amounts of phenol and the sulfates, phosphates, nitrates, carbonates, chlorides, and oxides of calcium, iron, copper, potassium, and sodium. The article was alleged to be misbranded because of false and misleading statements in the accompanying leaflet entitled "More-Milk," regarding the efficacy of the article in the cure, mitigation, treatment, or prevention of worms in hogs, and in insuring healthy hogs.

Analysis of the Mor-Milk for Calves showed the product consisted of a pink powder containing, chiefly, starch, protein, water, crude fiber, and small amounts of the phosphates, carbonates, chlorides, and oxides of calcium, iron, and sodium. The article was alleged to be misbranded because of false and misleading statements in the above-mentioned leaflet regarding the efficacy of the article in the cure, mitigation, treatment, or prevention of scours in calves.

Analysis of the Mor-Milk for Poultry showed that the product consisted of a white powder containing, chiefly, starch, protein, sugars, crude fiber, and small amounts of phenol and the sulfates, phosphates, nitrates, carbonates, chlorides, and oxides of calcium, iron, copper, potassium, and sodium. The article was alleged to be misbranded (1) because of false and misleading statements in the accompanying circular entitled, "What Have You Got That I Haven't Got," regarding the efficacy of the article in insuring the good health of baby chicks to the adult stage; (2) because of false and misleading statements in the circular regarding the efficacy of another drug, "Chick Mash," in the maintenance of health and thriftiness in chicks, and in the treatment or prevention of coccidiosis, and the efficacy of a food, "Egg Mash," in causing the production of the maximum number of eggs, and in maintaining health in poultry flocks; and (3) because of false and misleading statements in the accompanying circular entitled "Mor-Milk," regarding the efficacy of another drug, "Mor-Milk For Pigs and Hogs," in keeping worms in hogs at a minimum, and as a cheap insurance for healthy hogs. It was alleged to be further misbranded in that it was not designated solely by a name recognized in an official compendium, and was fabricated from two or more ingredients, one of which was "Special Fowl Remedy Mother Vance Compound," and the label of the article did not bear a statement of the active ingredients contained in the "Special Fowl Remedy Mother Vance Compound."

The articles, with the exception of the Mor-Milk for Poultry, were also alleged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in the notices of judgment on foods.

On October 16, 1944, the defendant having entered a plea of guilty, a fine of $50 on each count, a total fine of $450 and costs, was imposed.

1342. Misbranding of G. T. A. Cattle Mineral, and Superior Chemicals. U. S. v. 113 Bags of Cattle Mineral, 84 Cans, 198 Bags, and 250 Bags of Superior Chemicals, and an unknown number of Circulars. Decree of condemnation. Products ordered released under bond. (F. D. C. No. 11155. Sample Nos. 8225-F to 8228-F, incl.)

On November 23, 1943, the United States attorney for the District of North Dakota filed a libel against 113 100-pound bags of G. T. A. Cattle

Mineral, and 84 100-pound cans and 448 100-pound bags of Superior Chemicals, and an unknown number of circulars, at Fargo, N. Dak., alleging that the Cattle Mineral and a portion of the Superior Chemicals had been shipped from Minneapolis, Minn., by the Farmers Union G. T. A. Mills, Inc., between the approximate dates of January 30 and July 10, 1943, and that the remainder of the Superior Chemicals had been shipped from Denver, Colo., by the Superior Products Co., on or about May 18, 1943. The articles were labeled in part: "G. T. A. Cattle Mineral," "Sheep Special * * * Superior Chemicals," or "Superior Chemicals * * * [Pictures of a horse, sheep, ass, shorthorn, pig, and bull]."

Analysis of the Cattle Mineral disclosed that it consisted essentially of a mixture of mineral substances, charcoal, and a small proportion of molasses, and that it contained not more than 4.89 percent of phosphorus and not more than 0.057 percent of iodine. It was alleged to be misbranded in that the statements on its label, "Phosphorus (P), not less than 5.80% * * * Iodine (I), not less than .112%," were false and misleading as applied to the article, which contained less than the declared amounts. The article was alleged to be further misbranded because of false and misleading statements in the accompanying circular entitled, "Feed G. T. A. Mineral Supplement for Sound Bones Good Health Added Profits," regarding the efficacy of the article in the treatment of swollen joints, stiffness in legs, lowered milk production, lameness, poor appetite, lack of nerve control, pale blood and skin color, and anemia; and in the treatment of bloat and worms in sheep, thin flesh, abortion, and weak calves in cattle, paralysis of sows, thumps in hogs, goiter and stunted growth in lambs, and leg weakness, poor hatchability of eggs, roup, cholera, and other diseases of poultry.

Analysis of the Superior Chemicals disclosed that a portion consisted essentially of salt, 59 percent, calcium carbonate, 24 percent, sulfur, 3 percent, and small amounts of other mineral substances, charcoal, and turpentine oil; that the product in the 198-bag lot consisted essentially of 56 percent salt, 6.6 percent sulfur, charcoal, calcium carbonate, and other mineral substances; and that the product in the 250-bag lot consisted essentially of 58 percent salt, and other mineral substances including sulfates, charcoal, and 3.6 percent of sulfur. The article was alleged to be misbranded because of false and misleading statements in the circular entitled "Superior Chemicals for Livestock," regarding the efficacy of the article to prevent and correct chemical and mineral deficiencies, aid digestion, eliminate abortion, neutralize acids, decrease sheep death rate, increase profits, grow stronger and bigger calves, control worms in pigs, repel flies, ticks, and other external parasites, increase production of beef, pork, mutton, wool, finer offspring, milk, and butter, and remove and destroy intestinal parasites.

On January 21, 1944, the Farmers Union G.T.A. Mills, Inc., claimant, having admitted the material allegations of the libel, judgment of condemnation was entered, and it was ordered that the circulars be destroyed and that the products be released under bond to be brought into compliance with the law, under the supervision of the Food and Drug Administration.

1343. Misbranding of Ko-Ex-7. U. S. v. 153 Cartons of Ko-Ex-7. Default decree of condemnation and destruction. (F. D. C. No. 11244. Sample Nos. 11896-F, 29784-F.)

On December 6, 1943, the United States attorney for the Northern District of California filed a libel against 153 cartons of Ko-Ex-7 at San Francisco, Calif., alleging that the article had been shipped on or about April 27, 1943, from Buffalo, N. Y., by the Sterling Research Corporation; and charging that it was misbranded.

Examination of a sample disclosed that the article contained approximately 21.5 percent of ferrous sulfate, 1.23 percent potassium iodide, a nitrate, a borate, and plant material including a large proportion of wheat.

The article was alleged to be misbranded because of false and misleading statements on its containers and on accompanying charts, designated as "Mastitis Control Charts," which represented and implied that the article would be effective in the correction of faulty metabolism and in the cure, mitigation, treatment, prevention, and control of mastitis in cows, whereas it would not accomplish the results claimed. The article was alleged to be misbranded further in that the statement on its label, "Contents 16 Ounces," was false and misleading as applied to the article, which was short-weight.

On September 23, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1344. Misbranding of Heberlings Mineral Mixture with Yeast. U. S. v. 10 Bags of Heberlings Mineral Mixture with Yeast. Default decree of condemnation and destruction. (F. D. C. No. 12457. Sample No. 72147-F.)

On or about June 5, 1944, the United States attorney for the Eastern District of Missouri filed a libel against 10 100-pound bags of the above-named product at Oran, Mo., alleging that the article had been shipped on or about April 5, 1944, from Bloomington, Ill., by the G. C. Heberling Co.

The bag label of the article bore the following statement of composition: "Ingredients: * * * Limestone, Special Steamed Bone Meal, Soft Rock Phosphate, Salt, Soda Bicarbonate, Ferric Oxide, Ferrous Sulfate (Copperas), Copper Sulfate, Manganese Sulfate, Potassium Iodide (Stabilized), Irradiated Yeast (For Vitamin D), Oil of Anise, Cobalt Sulfate, Zinc Sulfate, Dry Yeast, Vegetable Oil."

The article was alleged to be misbranded because of false and misleading statements on the shipping tag and in the leaflet entitled "Livestock and Poultry Manual," enclosed in the bag containing the article, regarding its efficacy in increasing pork, beef, and egg production, saving feed, cutting losses due to various disease conditions, maintaining health of the animals, and acting together with niacin as a preventive of the specific infectious disease condition of pigs known as necro, as well as scours in calves.

On July 19, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1345. Adulteration and misbranding of Muco Spray. U. S. v. 125 Containers of Muco Spray. Default decree of condemnation. Product ordered disposed of by the United States marshal. (F. D. C. No. 12209. Sample No. 40240-F.)

On April 22, 1944, the United States attorney for the District of South Dakota filed a libel against 13 12-ounce bottles, 36 36-ounce bottles, 48 ½-gallon containers, and 28 1-gallon bottles or jugs of Muco Spray, at Sioux Falls, S. Dak., alleging that the article had been shipped on or about January 5, 1944, by the Iowa Master Breeders, Inc., from Sioux City, Iowa; and charging that it was adulterated and misbranded.

Analysis showed that the article was a liquid containing alcohol, formaldehyde, eucalyptol, menthol, turpentine, creosote, and a green coal-tar dye.

The article was alleged to be adulterated in that it contained, for purposes of coloring only, a green coal-tar color that had not been listed for use in drugs in accordance with the regulations, and was other than one from a batch that had been certified.

It was alleged to be misbranded in that the statements on its label, "For Relief of Coughs, Colds and Bronchitis in Poultry * * * In extreme cases * * * This vapor is very penetrating and effective," were false and misleading since the article, when used as directed, would not be effective for the relief of such disease conditions in poultry; it would not be effective in extreme cases; and it would not be an effective, penetrating spray in the prevention or treatment of the disease conditions for which it was recommended.

On May 22, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered disposed of by the United States marshal. It was destroyed.

1346. Misbranding of Criticoce Mash. U. S. v. 30 Bags of Criticoce Mash and a quantity of Leaflets. Default decree of condemnation. Product ordered delivered to an institution; leaflets ordered destroyed. (F. D. C. No. 12304. Sample No. 77861-F.)

On May 2, 1944, the United States attorney for the Eastern District of Pennsylvania filed a libel against 30 100-pound bags of the above-named product and a quantity of leaflets entitled "Criticoce Mash A Scientific Aid in the Control of Coccidiosis in Poultry," at Lansdale, Pa., alleging that the article had been shipped on or about March 31, 1944, by Schultz, Baujan & Co., from Beardstown, Ill.; and charging that it was misbranded.

The labeling of the article indicated that it consisted of a mixture of common feedstuffs with added vitamins A and D and calcium carbonate.

The article was alleged to be misbranded because of false and misleading statements on its label and in the accompanying leaflets which represented and suggested that the article was effective in the prevention or destruction of the parasite that causes coccidiosis in poultry.

On June 2, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to a public institution

after destruction of the leaflets and obliteration of the reference to coccidiosis appearing on the label.

1347. Misbranding of Apco Apcolene, and Apco Brooder and Litter Spray. U. S. v. 11 Bottles and 13 Bottles of Apco Apcolene, 5 Bottles of Apco Brooder and Litter Spray, and a number of leaflets. Default decree of condemnation and destruction. (F. D. C. No. 12915. Sample Nos. 40527-F to 40529-F, incl.)

On July 13, 1944, the United States attorney for the Northern District of Iowa filed a libel against 11 1-quart bottles and 13 8-ounce bottles of Apco Apcolene, 5 1-quart bottles of Apco Brooder and Litter Spray, 58 leaflets entitled "Fight Coccidiosis," and 55 leaflets entitled "Mycosis Fungi," at Waterloo, Iowa, alleging that the articles of drugs had been shipped on or about April 10, 1944, by the American Products Co., Inc., from Kansas City, Kans., and that, when introduced into and while in interstate commerce, they were accompanied by the leaflets.

Examination disclosed that the Apco Apcolene consisted essentially of copper, iron, mangenese, and magnesium sulfates, and propylene glycol, colored with FDC Red No. 2; and that the Apco Brooder and Litter Spray consisted essentially of coal-tar hydrocarbons, pine oil, and 0.23 percent of phenolic compounds.

The articles were alleged to be misbranded because of false and misleading statements and designs in the accompanying leaflets regarding the efficacy of the products in the treatment of coccidiosis, blackhead, and fungus diseases of poultry.

On August 1, 1944, no claimant having appeared, judgment of condemnation was entered and the products, together with the leaflets, were ordered destroyed.

1348. Misbranding of Sep-Tone. U. S. v. 12 Pint Bottles, 9 Quart Bottles, 3 Half-Gallon Bottles, and 2 Gallon Jugs of Sep-Tone. Default decree of condemnation and destruction. (F. D. C. No. 13027. Sample No. 72064-F.)

On July 24, 1944, the United States attorney for the Southern District of Illinois filed a libel against the above-mentioned quantities of Sep-Tone at Madison, Ill., alleging that the article had been shipped on or about June 24, 1944, by the Dolan Laboratories, from St. Louis, Mo.

Examination showed that the article consisted essentially of water, with small amounts of potassium dichromate, sodium, zinc, and copper sulfocarbolate, ammonium chloride, and an iodide.

The article was alleged to be misbranded in that the statements in its labeling, "Sep-Tone, A High Grade Astringent Intestinal Antiseptic For Medicating The Drinking Water. * * * Its use is indicated in the treatment of enteritis, Cholera, Typhoid, Colds, coccidiosis, Bronchitis and other bacterial infections. * * * Many poultrymen find that it pays to feed it continually for its antiseptic properties. * * * For Fowls out of condition use 2 tablespoonfuls to each gallon of water until improvement is noted," were false and misleading since the article had no value in the treatment of septic conditions; it was not a tonic nor an antiseptic; and it was of no value in the prevention or treatment of any disease condition of poultry.

On August 23, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1349. Misbranding of Erosionex. U. S. v. 54 Bags of Erosionex. Default decree of condemnation and destruction. (F. D. C. No. 12511. Sample No. 76937-F.)

On June 8, 1944, the United States attorney for the District of New Jersey filed a libel against 54 bags, each containing 25 pounds, of Erosionex at Newark, N. J., alleging that the article had been shipped on or about January 5, 1944, from Binghamton, N. Y., by the Daily Mills, Inc.

The label on the article indicated that it consisted of a mixture of common feedstuffs with added vitamin A and D feeding oils, extract nux vomica, oleoresin capsicum, zinc phenolsulfonate, red dog, sodium phenolsulfonate, calcium carbonate, kamala, copper sulfate, salt, calcined phosphate rock, and manganese sulfate.

The article was alleged to be misbranded because of false and misleading statements and designs on the bag label and in the accompanying circular entitled, "Double DD Diamond Ready-Mixed Erosion Ex For All Poultry," regarding its efficacy in preventing and curing mold and other infections in poultry.

On August 14, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1350. Misbranding of Hunt Club Dog Food. U. S. v. 165 Cases of Dog Food. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 11160. Sample No. 50110-F.)

On November 24, 1943, the United States attorney for the Western District of Pennsylvania filed a libel against 165 cases, each containing 10 5-pound bags, of dog food at Pittsburgh, Pa., alleging that the article had been shipped on or about October 23, 1943, from Buffalo, N. Y., by the Maritime Milling Co.; and charging that it was misbranded. The article was labeled in part: "Hunt Club Dog Food."

Examination of a sample disclosed that the article consisted essentially of cereals and other material, including ground wheat, ground corn, ground oats, ground soya beans, and ground alfalfa, and small amounts of ground bone, charcoal, and meat tissues.

The article was alleged to be misbranded in that the statements on the label, " * * * Contains everything needed for Vibrant Health, Robust Vigor and a Luxurious Coat * * * Owners Report These Results from Hunt Club feeding Vibrant Health Strong Bone Formation Sound Teeth Pleasant Breath A Thick, Glossy Coat Absence of Eczema and Other Skin Disorders. Freedom from * * * other Nutritional Deficiency Diseases. Added resistance to Colds and Distemper," were false and misleading since use of the article would not accomplish the results and benefits suggested or implied.

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in the notices of judgment on foods.

On March 10, 1944, the Maritime Milling Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 1301 TO 1350

PRODUCTS

[1] Prosecution contested. Contains instructions to the jury.

SHIPPERS AND MANUFACTURERS

[1]Prosecution contested. Contains instructions to the jury.

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